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TITLE: Development of Subischial Prosthetic Sockets with Vacuum-Assisted Suspension for Highly Active Persons with Transfemoral Amputations

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14. ABSTRACT

The purpose of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. The Specific Aims are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop durable liners and sealing sleeves; A3. Develop/identify an appropriate vacuum pump; A4. Evaluate system performance with military amputees; and A5. Develop education materials. For Aims 1 and 2, we have created a finite element model to assess our system and investigated different liners and sealing solutions. For Aim 3, we have identified options for vacuum pumps, characterized currently available pumps, and developed a hybrid mechanical-electrical pump design for persons with transfemoral amputation. We have IRB approval in place for Aim 4 which is scheduled to begin in Year 3. For Aim 5, we have developed a computer program to quantify socket rectifications and begun development of education materials to facilitate dissemination of this technique.

15. SUBJECT TERMS
Transfemoral amputation, sub-ischial socket, prosthesis, vacuum-assisted suspension

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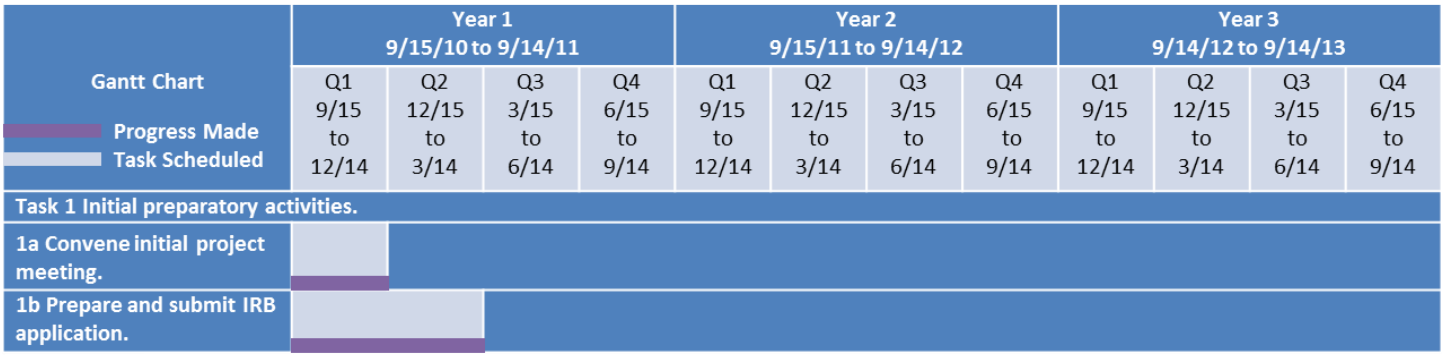
INTRODUCTION

The objective of this project is to develop a highly flexible sub-ischial prosthetic socket with assisted-vacuum suspension for highly active persons with transfemoral amputation. We are focused on developing prosthetic socket technology that will enhance user activity by maintaining residual limb volume; improving active range of motion of the hip; improving coupling between the limb and socket; and increasing comfort during sitting, standing, walking, and running in highly active transfemoral prosthesis users. The Specific Aims of this project are to: A1. Develop a highly flexible socket with sub-ischial trim lines; A2. Develop liners and sealing sleeves that are durable for highly active users; A3. Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis; A4. Evaluate system performance with transfemoral prosthesis users; and A5. Develop education material for sub-ischial socket design. Human performance will be evaluated at the Center for the Intrepid in the third year of funding. For Aims 1 and 2, we are using engineering analysis and an advanced manufacturing approach to improve the socket and liner. For Aim 3, we have identified options for vacuum pumps, characterized commercially available vacuum pumps, and designed a hybrid mechanical/electrical pump for persons with transfemoral amputation. For Aim 4, highly active persons with unilateral transfemoral amputation will be recruited to evaluate system performance and will provide important feedback on the design. For Aim 5 we are developing education materials based on quantification of the socket rectification and fabrication process. This project provides an improved prosthetic socket technology for the clinical care of highly active military service persons with transfemoral amputation. Increased comfort, hip range of motion and coupling between the residual limb and prosthesis will result in increased functional performance of individuals with combat-related transfemoral amputations. Furthermore, improvements in socket comfort and coupling would benefit all persons with transfemoral amputation, regardless of their activity level.

BODY: PROJECT PROGRESS

What follows is a description of the work conducted during Year 2 of our project. Our progress is presented with respect to the Aims and Tasks described in our grant application, with progress on each task indicated on the corresponding section of the approved statement of work (Gantt chart). Overall, we have made good progress on the tasks in Aims 1 and 2, completed most of the tasks in Aim 3, begun work on Aim 4, and made progress on the tasks in Aim 5. The poster presented at the Military Health System Research Symposium provides a succinct overview of how the work of Aims 1 and 5 inform each other (**Appendix A, Figures A & B**). Our material testing system (MTS) was finally made fully operational in April 2012, which allowed us to forge ahead with Tasks 2a, 4a and 4b. Overall, we were able to get caught up on Tasks 2b, 2c, 10a, 10b, 10c and 11a; partly caught up on Tasks 4b, 4d, and 4e; and remain ahead on Tasks 12a-d. Progress on Task 3 remains delayed but we have a plan in place to complete Task 3 by the end of Year 3.

Task 1 Initial preparatory activities



1a Convene initial project meeting: *This task is complete.*

1b Prepare and submit IRB application: *This task is complete.* All components for this project have received IRB approval. IRB approvals are summarized in **Table 1**.

NU Project No.	Title	Date Approved
STU00032753 (Umbrella)	Development of Sub-Ischial Prosthetic Sockets with Assisted-Vacuum Suspension for Highly Active Persons with Transfemoral Amputations	NU IRB 6/23/10 HRPO 10/26/10
STU00033437	Development of highly flexible sub-ischial socket and durable liner for highly active transfemoral prosthesis users (Aims 1 & 2)	NU IRB 8/6/10 HRPO 8/18/10
STU00033443	Characterize vacuum pump requirements for persons with transfemoral amputation (Aim 3)	NU IRB 7/26/10 HRPO 8/10/10
STU00033446	Performance Evaluation of Sub-Ischial Socket for Highly Active Persons with Transfemoral Amputation (Aim 4)	BAMC IRB 7/31/11 HRPO 9/22/11 NU IRB 1/13/12
STU00033448	Quantification of Residual Limb Model Rectifications for Sub-Ischial Sockets (Aim 5)	NU IRB 7/2/10 HRPO 7/28/10

Table 1 Summary of IRB protocols.

Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users

Task 2 Design and simulation of sub-ischial socket

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 2 Design and simulation of sub-ischial socket.												
2a Reverse engineer hand-fabricated socket to build 3D CAD model.												
2b Perform mechanical simulations on hand fabricated 3D model.												
2c Develop simple parametric 3D CAD model using "ladle frame" design.												
2d Perform mechanical analyses.												
2e Develop 3D CAD rectification techniques for semi automated design of "ladle frame" socket from digitized limb shape.												

Task 2a Reverse engineer hand-fabricated socket to build 3D CAD model and FE model: *This task is complete.*

Task 2b Perform mechanical simulations on hand-fabricated 3D model: *This task is complete.* The goal of this task was to establish baseline values for the mechanical and material properties of the rigid frame component of the hand-fabricated socket system. In conjunction with Task 4b (socket strength and deflection tests) and Task 4c (indentor tests of elastomers), this test contributes to the characterization of the mechanical behavior of the socket and its components in response to load. In anticipation of the high failure loads of the rigid socket frame, a three-point flexural test was performed in accordance with specifications of the testing standard ASTM D790-10. Samples were installed in the testing fixtures (Figure 1) and compressive loads applied until failure of the material. The flexural modulus values for the different carbon fiber reinforced samples are shown in Table 1.

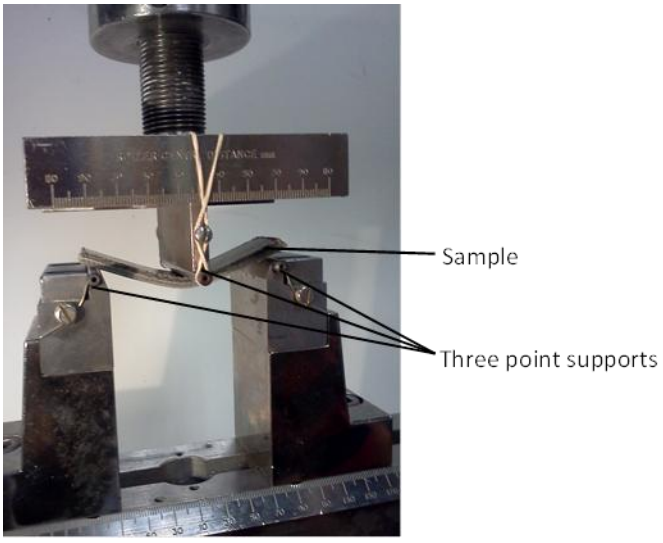


Figure 1 Flexural test of carbon-fiber reinforced rigid frame material.

Table 1 Flexural modulus values for carbon fiber reinforced socket frame material.

Sample	1	2	3	4	5	6	7	8	9	10	11	12
Modulus (MPa)	3149.98	3685.03	5993.92	2477.64	4936.90	4977.88	6473.74	6254.13	4242.26	6589.19	5877.43	3571.13
										Mean		4852.43
										Standard Deviation		1350.96

Task 2c Develop a simple, parametric 3D CAD model using "ladle-frame" design: *This task is complete.* The parameters identified as most critical to the performance of the socket were the socket frame design and the socket frame thickness. 3D CAD models of two rigid frame designs are shown in Figure 2.

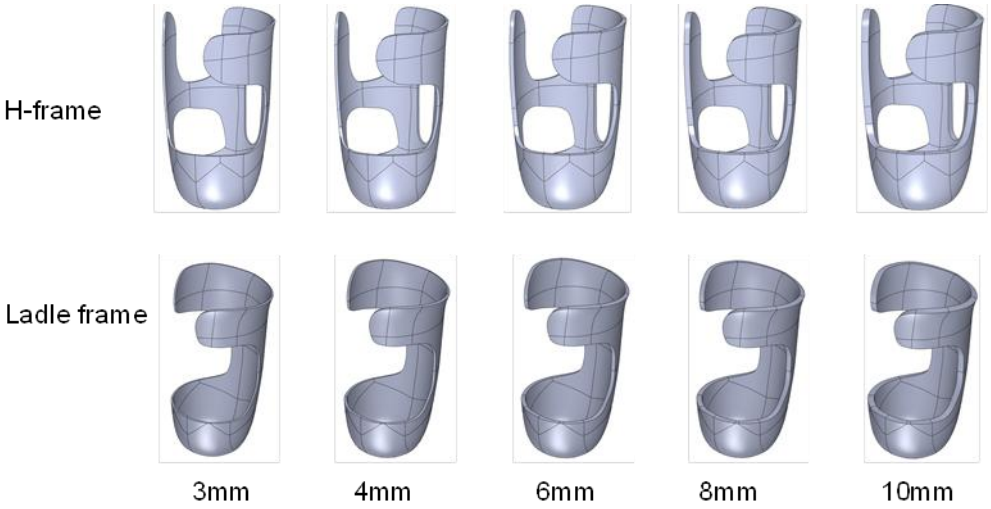


Figure 2 3D CAD model of the rigid frame of the prosthetic socket. The parameters varied are the frame design (H-frame and Ladle frame) as well as the thickness of each frame type (ranging from 3mm to 10mm).

Task 2d Perform mechanical analyses: *This task is in progress.* Having defined analysis regions based on functional areas of the frame (Figure 3) we have used the model to qualitatively and quantitatively assess the stress distribution for different frame designs (Figures 4 and 5). The model is now ready to be used to assess the effect of different socket parameters, e.g. frame thickness, on stress distribution and function. A number of the socket 3D CAD models of Figure 2 have already been evaluated. To complete this task, the remaining sockets need to be analyzed. Abstracts on these preliminary stress analyses have been accepted for presentation at the 2013 world congress of the International Society for Prosthetics and Orthotics (Appendix B) and the 2013 annual meeting of the American Academy of Orthotists and Prosthetists (Appendix C).

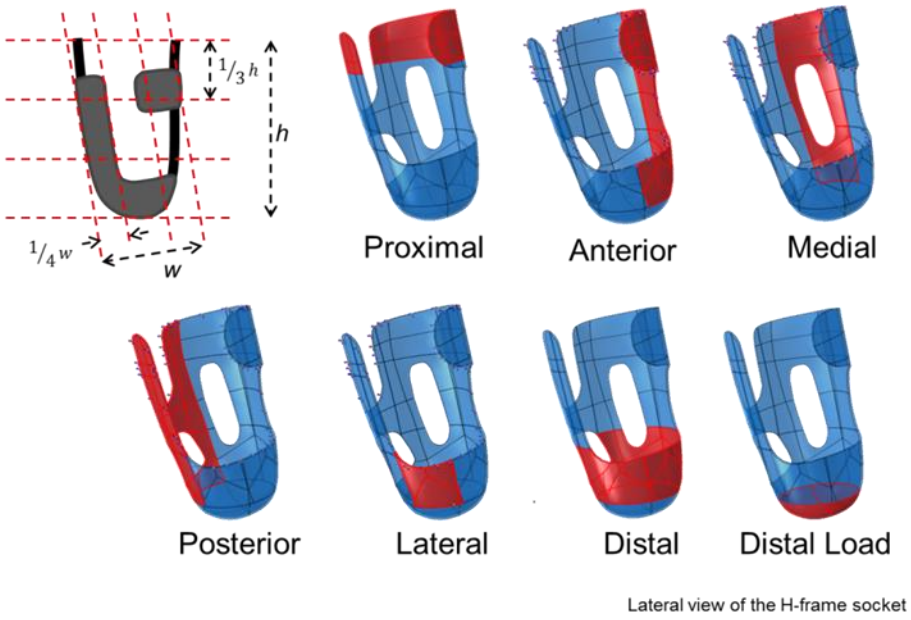
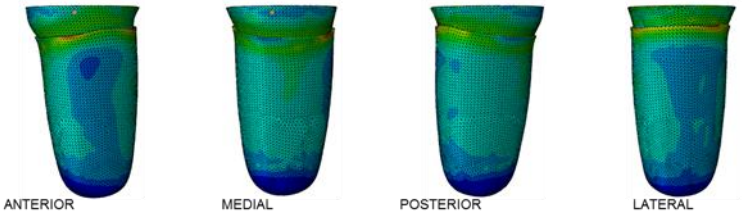


Figure 3 Analysis regions for the H-frame.

Completely rigid frame



Ladle frame

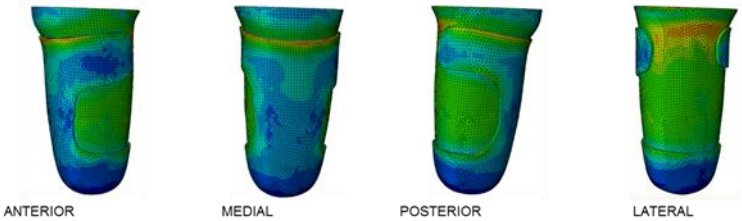


Figure 4 Qualitative analysis of stress distribution for different frame designs. Preliminary results demonstrate that different frame geometries have different effects on the socket stress distribution.

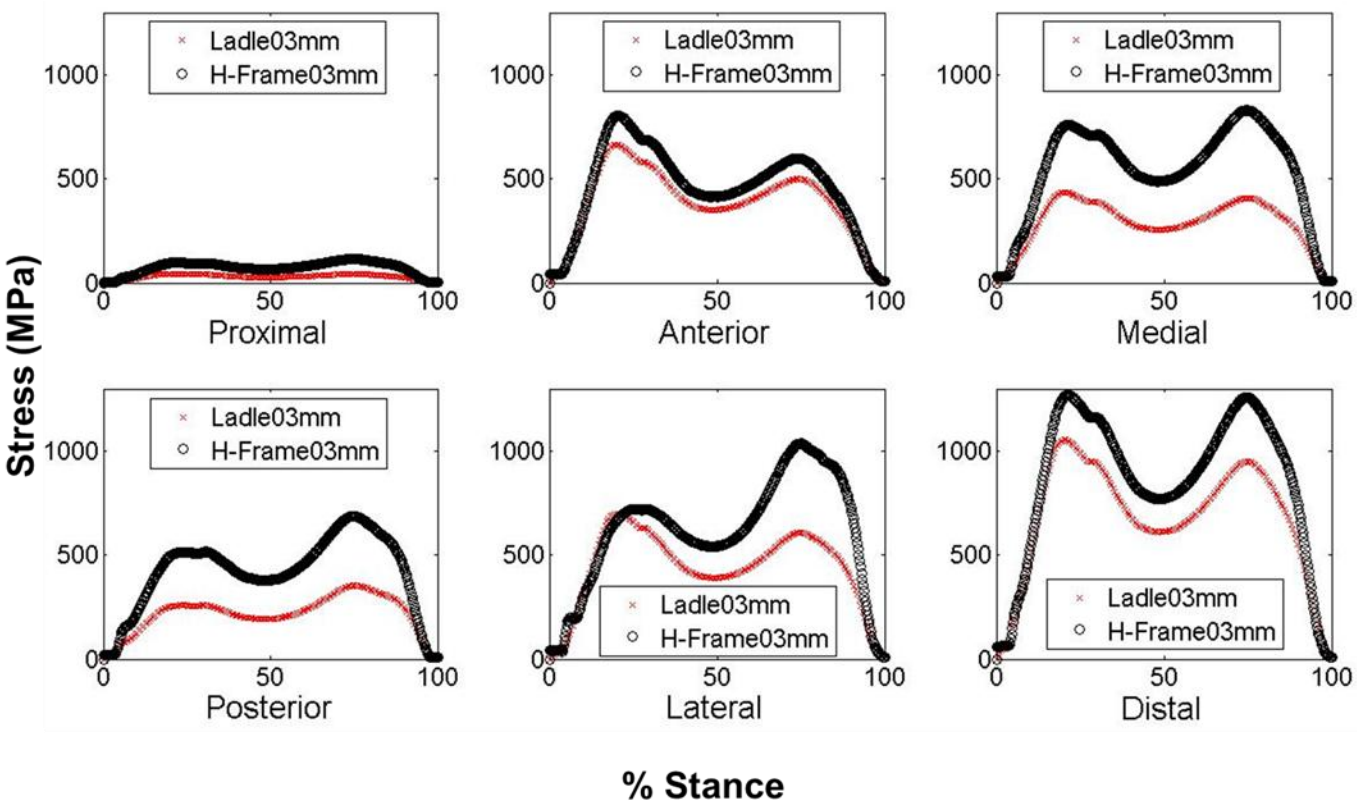


Figure 5 Qualitative analysis of stress distribution for different frame designs assessed by analysis regions shown in Figure 3.

Task 2e Develop 3D CAD rectification techniques for semi-automated design of "ladle-frame" socket from digitized limb shape: *This task is in progress.* With the FEA model in place, the remaining work is to input the information about limb, rectifications and frame shape from Task 11e (please refer to discussion under Task 11e) into the FEA model and demonstrate that it can be used to assess socket performance. Additionally, work is ongoing to incorporate more prosthetic socket loading scenarios in the computation model, with the goal of a more comprehensive simulation of socket performance at physiological loads reflective of a range of activity levels.

Task 3 Advanced manufacturing of sub-ischial sockets

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 3 Advanced manufacturing of sub-ischial sockets.												
3a Establish criteria and techniques for multi-shot cavity molds.												
3b Develop degassing techniques for liquid resin molding.												
3c Develop proximal brim vacuum seal.												
3d Develop mechanical interlocking molding techniques.												

Training with our Stratasys rapid prototyping system took place on 10/4/11. After discussion with our project officer, Dr Martinelli, it was agreed that a Masters level research assistant would be most helpful to furthering work on this task. Engineering graduate student Brian Robillard has been recruited to work on Tasks 3a, 3b and 3d over the coming academic year which coincides with Year 3 of the grant. Task 11e provides the basis upon which to proceed with automated fabrication as it will be the input data needed to create frames or molds for frames to be fabricated using fused deposition modeling or other automated techniques.

Task 3a Establish criteria and techniques for multi-shot cavity molds: *We are behind schedule on this task.*

Task 3b Develop degassing techniques for liquid resin molding: *We are behind schedule on this task.*

Task 3c Develop proximal brim vacuum seal: *This task is complete.* Our trials with internal sealing rings all led to a tourniquet effect on the residual limb, suggesting that the tension needed for our socket design may not permit a ring to be used safely and comfortably. The internal sealing ring was originally proposed as a way to address issues of liner wear observed due to reflection of the liner over the proximal brim of the socket. However, changes over the course of the project in both socket material and liner type have actually diminished the problem of liner durability. We have noted since moving to using Polytol for the sub-ischial sockets that liners are lasting longer. The more compliant Polytol material at the proximal brim does not cut into the reflected liner as quickly or to the same extent as did previous lamination materials. Completion of Task 4d and 4e will help confirm this observation. Also, when sitting, the posterior portion of the liner does not breakdown as quickly as it is no longer sandwiched between a hard socket and a hard seat.

We have also moved from using the Evolution liner to the Medi Relax liner. Our prosthetist Ryan Caldwell has consistently used the Medi Relax liner with Polytol sockets in clinical practice for over a year and confirms that liner durability has improved compared to his past experience with other liners and laminations. For example, previously those patients using Evolution liners would replace the liner every 3-4 months on average, whereas the Medi liner is lasting for over 6 months to date. This may in part be due to the presence of fabric on the outer surface of the liner.

Task 3d Develop mechanical interlock molding techniques: *We are behind schedule on this task.*

Task 4 Mechanical bench testing of sockets and liners

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 4 Mechanical bench testing of sockets and liners.												
4a Perform peel tests of bond strength.												
4b Perform socket strength and deflection tests.												
4c Perform indentor tests of elastomers.												
4d Perform sitting durability tests.												
4e Perform cyclic evacuation tests.												

Task 4a Perform peel tests of bond strength: *This task is complete.* The ASTM D 1876-08 (Standard Test Method for Peel Resistance of Adhesives 'T-Peel test') was used to assess the bond strength between subsequent polyurethane (PU) layers of the socket. In accordance with the standard, 10 samples of two bonded PU layers were prepared (Figure 6). Each sample was loaded into a universal testing system and tensile forces were applied to separate the different layers (Figure 7). The applied forces were monitored and have been plotted versus time for all 10 samples (Figure 8).

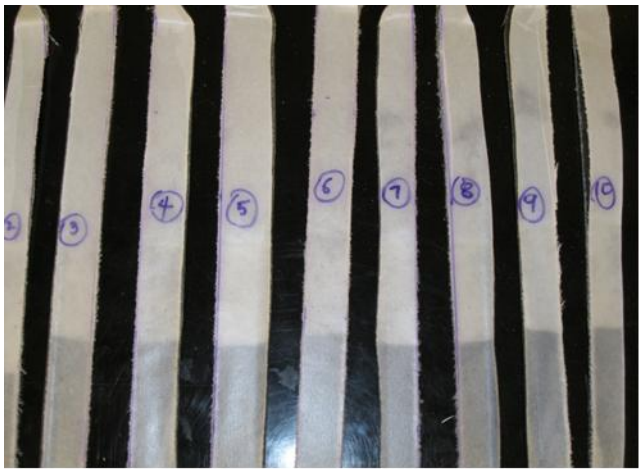


Figure 6 Bonded polyurethane-polyurethane samples. Dimensions are in accordance with ASTM D1876-08 specifications.

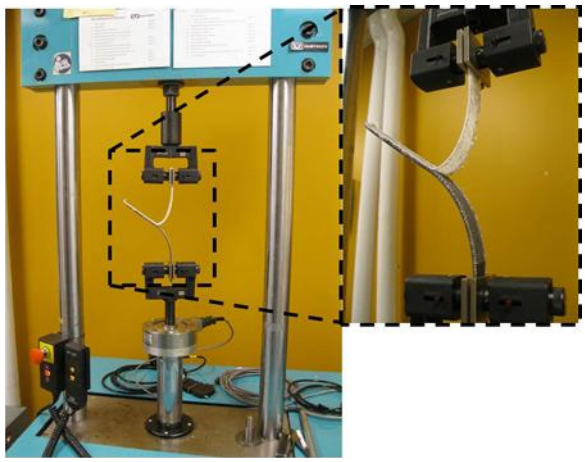


Figure 7 Peel test of polyurethane-polyurethane samples. The samples are attached to a universal testing system and subjected to tensile forces which separate the bonded material. The applied tensile forces are measured and recorded.

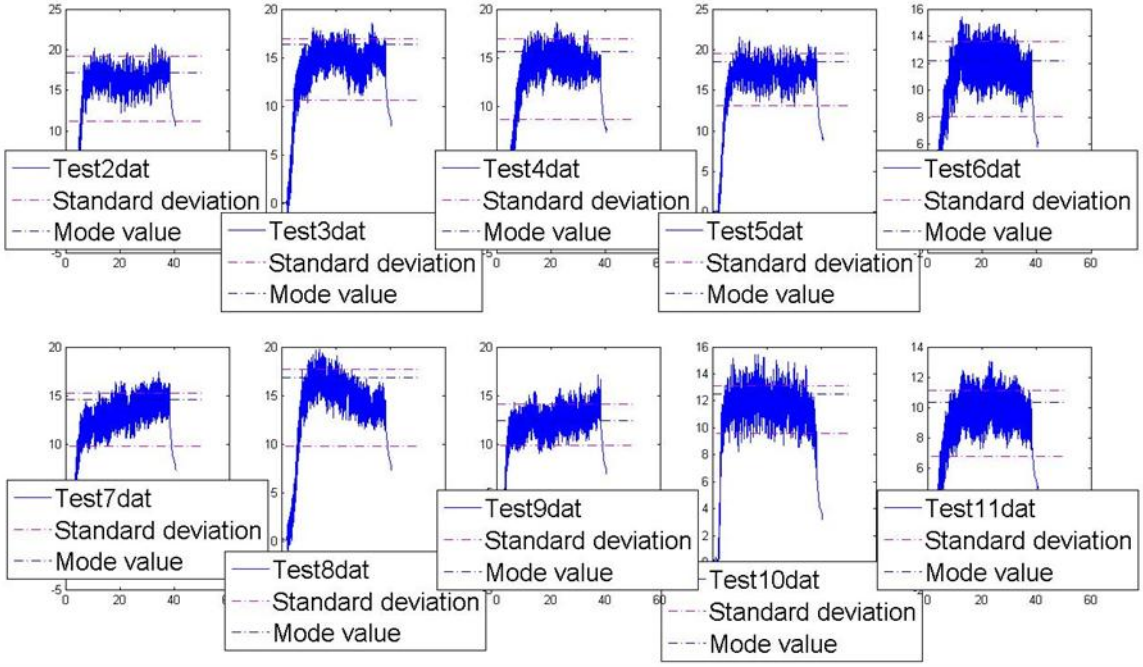


Figure 8 Applied forces on bonded polyurethane samples.

The most occurring force value (mode) was used as representative of the required force to peel the adjacent PU layers. Table 2 lists the force values of the different samples. An average force of 14.65 N (3.30 lbs) was required to separate the bonded materials.

Table 2 Peel force measurements for polyurethane-polyurethane samples.

Sample	1	2	3	4	5	6	7	8	9	10
Peel force(N)	12.52	10.36	17.14	16.39	15.61	18.53	12.20	14.54	16.86	12.38
								Mean		14.65
								Standard Deviation		2.54

Task 4b Perform socket strength and deflection tests: *This task is in progress.* During the course of this last year we became aware that Ohio WillowWood have developed testing apparatus and a protocol for testing of prosthetic socket strength for comparison across industry (Gerschutz et al., 2012), hence three sockets were fabricated and have been sent to Ohio WillowWood for strength testing. Results for our socket strength can then be compared to values in the literature.

Task 4c Perform indentor tests of elastomers: *This task is complete.* An indentor test of the socket elastomer material was originally proposed to establish values of material properties to use in full socket simulation. However, with a better understanding of the socket technology, it became clear that a tensile test will provide a better simulation of the actual loading condition of the socket during use. Specimens of the elastomer material were prepared (Figure 9) and tested in tension according to ASTM D638-10 (Figure 10). The modulus of each specimen was calculated (Figure 11) and are presented in Table 3.

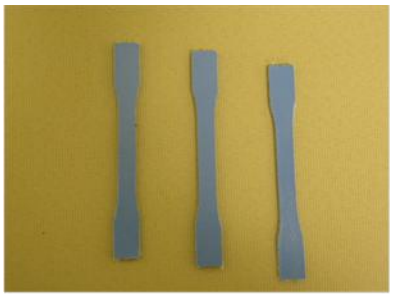


Figure 9 Dog bone specimen cut out of polyurethane elastomeric material. Specimen dimension are based on ASTM D638-10, Type IV specifications.

Figure 10 Elastomer dogbone samples installed in testing system clamps. Tensile forces were applied until specimen failure and extension was measured using an extensometer.

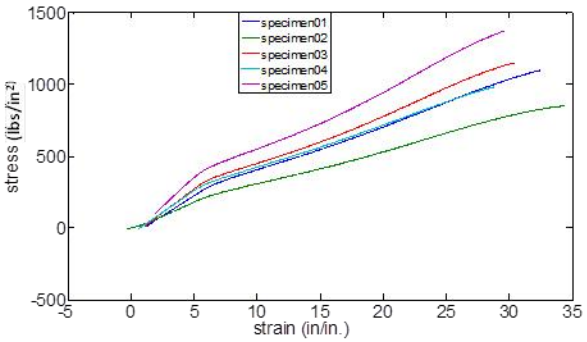


Figure 11 Stress versus strain plot of elastomeric socket material under tensile loads.

Table 3 Modulus values for elastomeric samples characterized using a tensile test.

Sample	Modulus (lb/in²)
1	34.26
2	25.29
3	36.28
4	35.18
5	41.56
Mean	34.51
Standard Deviation	5.26

Task 4d Perform sitting durability tests: *This task is in progress.*

Task 4e Perform cyclic evacuation tests: *This task is in progress.*

Initially, we believed the conditions mainly responsible for liner failure were repeated pinching and shear of the liner between the hard socket and a sitting socket (Task 4d) as well as stressing of the liner that occurs on the socket brim when vacuum is applied (Task 4e). More recent interactions with users of prosthetic liners suggest the primary mode of failure is a knife edge action of the brim of the rigid socket through the side of the liner. Hence, we have re-designed the testing approach for this task. The experimental protocol has been finalized (Appendix D) and samples are in the process of being procured.

Task 5 Solicit feedback from human subjects

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aims 1 & 2 Develop a highly flexible socket with sub-ischial trim lines and a durable liner for highly active users.												
Task 5 Solicit Feedback from human subjects.												
5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects.												

Task 5a Perform subject fittings with advance manufactured sockets. Assess results and obtain feedback from subjects: *This task is in progress.* We have recruited two highly active subjects with unilateral transfemoral amputation. For Subject 1 we have completed gait analysis in the sub-ischial socket as well as the ischial containment socket (see Appendix C for case study accepted for presentation at the 39th meeting of the American Academy of Orthotists and Prosthetists), and undertaken clinical assessment of different liners and sealing techniques. Subject 1 agreed to assist with videos and photos for the instructional manual that we are creating to support dissemination of the socket. Figure 12 demonstrates the range of motion the subject is comfortably able to achieve with the sub-ischial socket. For Subject 2, we have completed gait analysis in the ischial containment socket and the sub-ischial socket. Subject 2 had some issues of socket fit arise following loss of residual limb volume that we are currently addressing.

Figure 12 Range of motion in sub-ischial socket for subject 1.

Gait analyses of level walking at both normal and fast speeds suggest that the sub-ischial socket performs as well as conventional ischial containment sockets. One subject perceived greater comfort for sitting and walking in the sub-ischial socket, while the other subject perceived greater comfort for sitting and equal comfort for walking in the sub-ischial socket. Times to perform functional tests (Four Square Step Test and T-Test of Agility) were comparable between sockets. Gait analysis results are summarized in Appendix E.

Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis

Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 6 Determine range of volumes to be evacuated from transfemoral sockets of highly active prosthesis users.												
6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test).												
6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users.												
6c Compare results of 6a and 6b.												

Task 6a Evaluate time needed for vacuum pumps to evacuate known volumes (bench test): *This task is complete.* We repeated testing of the mechanical pumps with the MTS machine, and in particular for the P3 pumps, we used a new set of uncompressed functional rings. This testing was undertaken for the purposes of strengthening the data for publication. Initially, our MTS machine was unavailable, so we undertook testing using a hand actuated lever (Wood, 2011). This presented a limitation in terms of possible fatigue by the human tester that we addressed by repeating the testing protocol with our MTS machine once it was operational. The results between tests are comparable suggesting that fatigue did not unduly influence the original data. With regards to the P3 functional rings we had an issue arise during initial testing in that one of the rings arrived from the manufacturer pre-compressed and the other four did not. This may have influenced the results and hence we purchased an entire set of uncompressed rings in order to standardize this variable before testing.

Task 6b Evaluate time needed to evacuate sockets of transfemoral prosthesis users: *The originally planned portion of this task is complete and additional work is in progress.* We have collected and analyzed data from 14 subjects with unilateral transfemoral amputation. We are working to recruit additional subjects. However, our prosthetist, Ryan Caldwell, changed employer in December 2011, and we have had to wait for him to re-establish his referral base in order to recruit these additional subjects.

Task 6c Compare results of 6a and 6b: *This task is complete for initial data.*

Task 7 Characterization of mechanical and electrical pumps

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 7 Characterization of mechanical and electrical pumps.												
7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses.												
7b Characterize pumps based on cycles and time to pull specific vacuum levels.												
7c Publish a journal article on the characterization of the mechanical pumps.												

Task 7a Survey and collect all mechanical and electric pumps for use in lower limb prostheses: *This task is complete*.

Task 7b Characterize pumps based on cycles and time to pull specific vacuum levels: *This task is complete.*

Task 7c Publish a journal article on the characterization of the mechanical pumps: *This task is nearing completion.* A draft manuscript is currently being circulated among co-authors and will be submitted for publication by end of October 2012.

Task 8 Finalize vacuum pump design

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 3 Develop/identify an appropriate mechanical pump to create suitable vacuum for suspension of the prosthesis.												
Task 8 Finalize vacuum pump design.												

This task is complete. In June 2012, we filed a U.S. patent application titled "Vacuum pump systems for prosthetic limbs and methods of using same." At the same time, we also filed a PCT (foreign) patent application. Two prosthetic companies have expressed interest in the hybrid pump and we are in discussions with both regarding possible licensing of the technology. In addition, we have applied for supplemental funding from the FY2012 Joint Warfighter Medical Research Program to prototype and test the three hybrid vacuum pump embodiments described in the patent application. If funded, the testing protocol would provide the

characteristic vacuum evacuation profile for the hybrid pumps and allow objective performance comparison to existing commercially available vacuum pump designs.

Aim 4 Evaluate system performance with transfemoral prosthesis users

Task 9 Conduct performance evaluation with human subjects

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 4 Evaluate system performance with transfemoral prosthesis users.												
Task 9 Conduct performance evaluations with human subjects.												
9a Transfer socket casting and rectification skills/knowledge.												
9b Recruit and test human subjects.												
9c Publish results if appropriate.												

Task 9a Transfer socket casting and rectification skills/knowledge: *This task is in progress.* We are scheduled to visit BAMC at the end of October 2012 to cast and fit the first two subjects and in the process transition the socket fabrication and fitting techniques to BAMC prosthetists. However, this task began earlier than planned because our collaborators at BAMC requested that we share our preliminary education documents with them early so that they might address demand from an overwhelming number of military service personnel with bilateral transfemoral amputations who were dissatisfied with their current prostheses. Our BAMC collaborators indicated that they have tried our system on three patients and provided us with feedback regarding both our preliminary education documents and their experiences thus far. While initial fittings with two of the three patients were successful, neither patient continued to wear the sub-ischial socket after an initial trial phase. We believe that this may be due to (1) choice of liner which we had not finalized which we had not finalized at the time of BAMC's initial request or (2) the sockets having been fabricated using conventional rigid laminations since we were not ready to share with them the more flexible Polytol frame design at the time of BAMC's initial request. New fittings will address both these issues. Additionally, we incorporated feedback provided by John Fergason, CP, into a second version of our instructional manual which now includes a revised reduction algorithm and a sub-ischial socket measurement chart.

Task 9b Recruit and test human subjects: *This task is in progress.* Planning for this task with our collaborators at BAMC has begun. We are scheduled to visit BAMC at the end of October 2012 to cast and fit the first two subjects.

Task 9c Publish results if appropriate: *Not scheduled to start.*

Aim 5 Develop education materials for sub-ischial socket design

Task 10 Develop a quantification tool for socket rectifications

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs												
Task 10 Develop quantification tool for socket rectifications.												
10a Develop computer program to quantify socket rectifications.												
10b Develop shape registration scheme.												
10c Test program accuracy.												

Task 10a Develop computer program to quantify socket rectifications: *This task is complete.* A color-coded rectification scale was added to the program. The scale's units are in millimeters: negative numbers represent the amount of material removed during rectification and positive numbers represent the amount of material added. However, since no material is added during rectification, the positive coloring indicates areas where the modified shape is outside the unmodified shape. Positive coloring implies a misalignment when this occurs in the distal portion of the shape. In Figure 13, the scale indicates that a maximum of 6 millimeters was removed. There is also a large region where about 4 millimeters was removed. Outside of that region blending into the unmodified regions takes place (Figure 13).

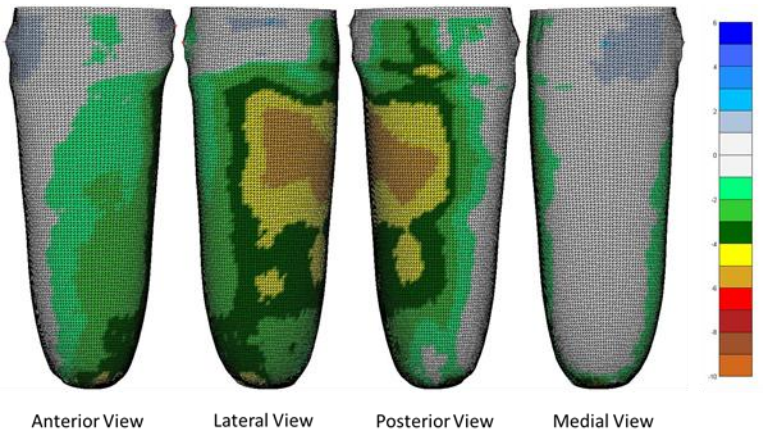
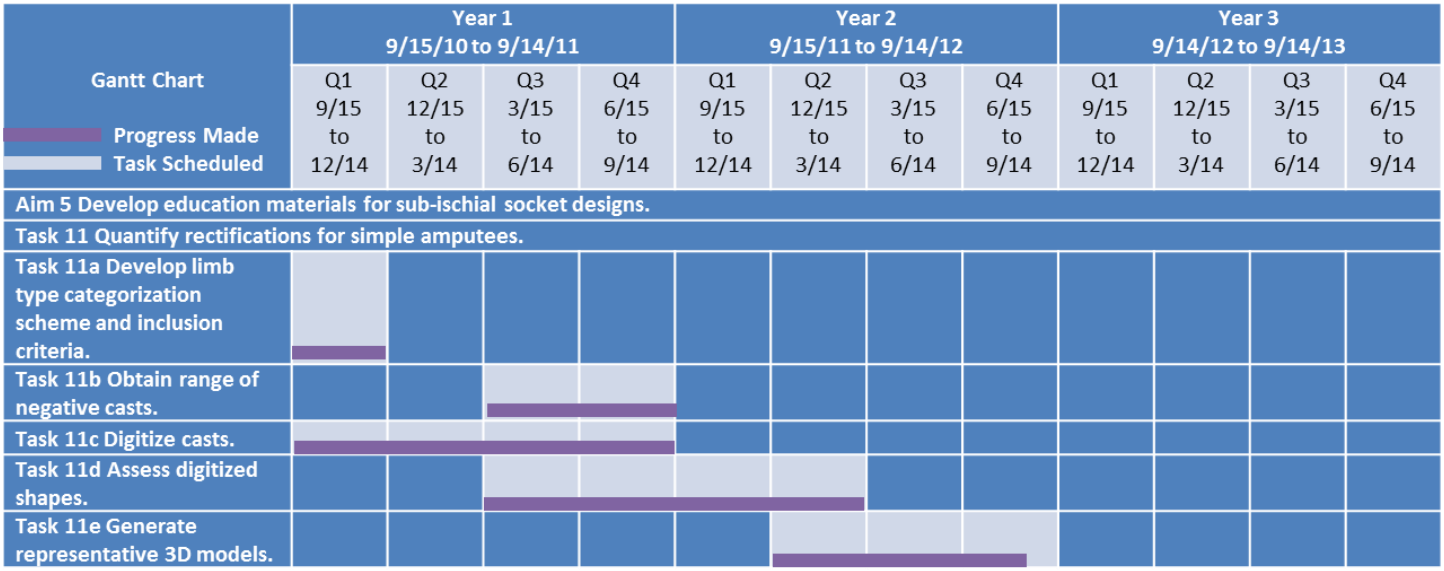


Figure 13 Quantification of mold rectification using a color-coded rectification scale.

Task 10b Develop shape registration scheme: *This task is complete.* The alignment of modified and unmodified shapes is the first step in quantifying the amount of rectification. We used an iterative closest point (ICP) algorithm to align the shapes. This algorithm seeks to minimize the difference between similar regions. So, we defined four regions that were not modified during rectification. Three regions were defined in the proximal portion of the positive model, and the fourth was placed along the medial wall.

Task 10c Test program accuracy: *This task is complete.* After alignment, the differences between the two shapes were calculated and color coded to indicate the location and degree of rectification (see Figure 13). The prosthetist who performed the rectifications confirmed the accuracy of the resulting models.

Task 11 Quantify rectifications for multiple amputees



Task 11a Develop limb type categorization scheme and inclusion criteria: *This task is complete.*

Task 11b Obtain range of negative casts: *The originally planned portion of this task is complete and additional work is in progress.* To date we have collected 26 casts. We are working to collect additional casts. However, our prosthetist, Ryan Caldwell, changed employer in December 2011, and we have had to wait for him to re-establish his referral base in order to collect these additional casts.

Task 11c Digitize casts: *The originally planned portion of this task is complete and additional work is in progress.* 15 pairs of casts have been digitized to date using the process described in Tasks 10a and 10b. We are waiting on additional casts from Mr Caldwell. Initially, we included casts from persons with knee disarticulation, but based on further discussion we've decided to exclude those casts from our current series as considerations regarding casting and rectification are different and may confuse initial adopters.

Task 11d Assess digitized shapes: *This task is complete.* See Appendix F for overview of digitized shapes. It is clear that rectifications are consistently confined to the proximal posterior and lateral portions of the mold and that they are more aggressive for limbs categorized as having "soft" tissues compared to limbs categorized as having "firm" tissues.

Task 11e Generate representative 3D models: *This task is in progress.* We investigated various 3D unwrapping techniques and how to implement them. The resulting code is used to generate 2D rectification maps. These maps can be used for identifying common modification patterns and creating templates for automated socket rectification.

Automation of the socket rectification process requires the creation of tools to handle 3D object manipulation (e.g., rotating, sculpting, and cutting), file storage and manipulation, and a user-friendly graphical interface. Attempting to create all these tools from scratch is a daunting task. So, we identified an existing program that would reduce the coding burden and provide functional and optimized tools for 3D modeling. We settled on Blender, a free, open source 3D modeling and animation package with powerful 3D mesh and modeling tools and Application Programming Interface (API) to write custom code to alter the interface, add new tools, and streamline multi-step processes to just a single button click. Blender is useful because it provides a single interface for socket rectification and frame design. Blender currently has the ability to import many 3D file formats like STL, OBJ and PLY. However, in prosthetics, the standard file format is AOP, and Blender doesn't recognize this file structure. So, we've created a custom script for handling prosthetic shapes.

The first step in displacement mapping is the unwrapping of the 3D shape. Once imported, the socket can be easily unwrapped by first placing cut lines on the medial wall and distal cap. The vertical cut line is placed on the medial wall because it is best to place cut lines in areas that remain relatively constant during mapping. Also, this placement ensures that the lateral wall is at the center of the 2D map, which means that our displacement pattern will not be interrupted by the seam. Unwrapping the socket leads to some distortions, but since a socket is similar in shape to a cone, the distortions are minimal. Grayscale maps can be created by painting directly onto the 3D shape and/or 2D map. Grayscale maps alter the amount of displacement based on the color value each vertex possesses after painting. Black means no displacement, and white means maximum displacement. The displacements in the transition region are scaled between zero and the maximum user-specified value. The anterior and medial walls remain constant; deformation occurs on the posterior and lateral walls (Figure 14). The final step, which is currently underway, is to explore methods to fully automate the process or use a series of curves to define the frame's shape.

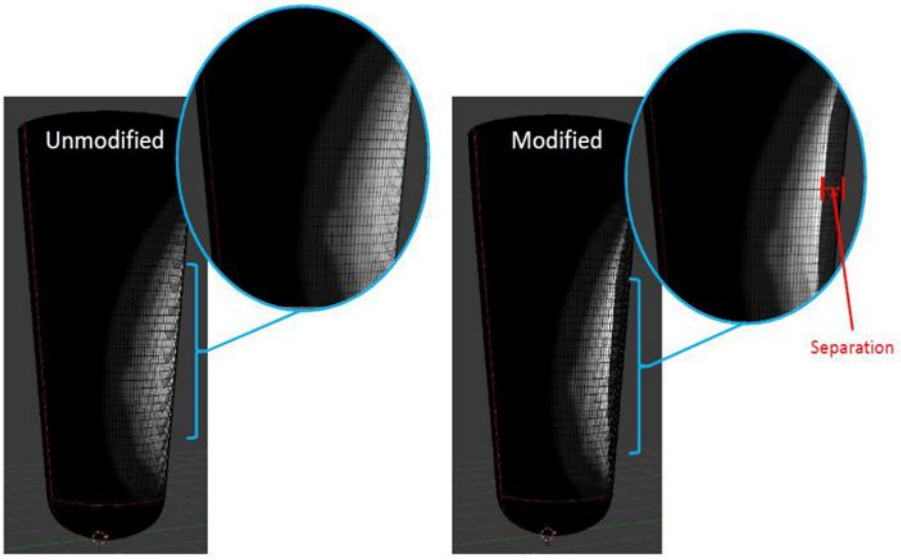
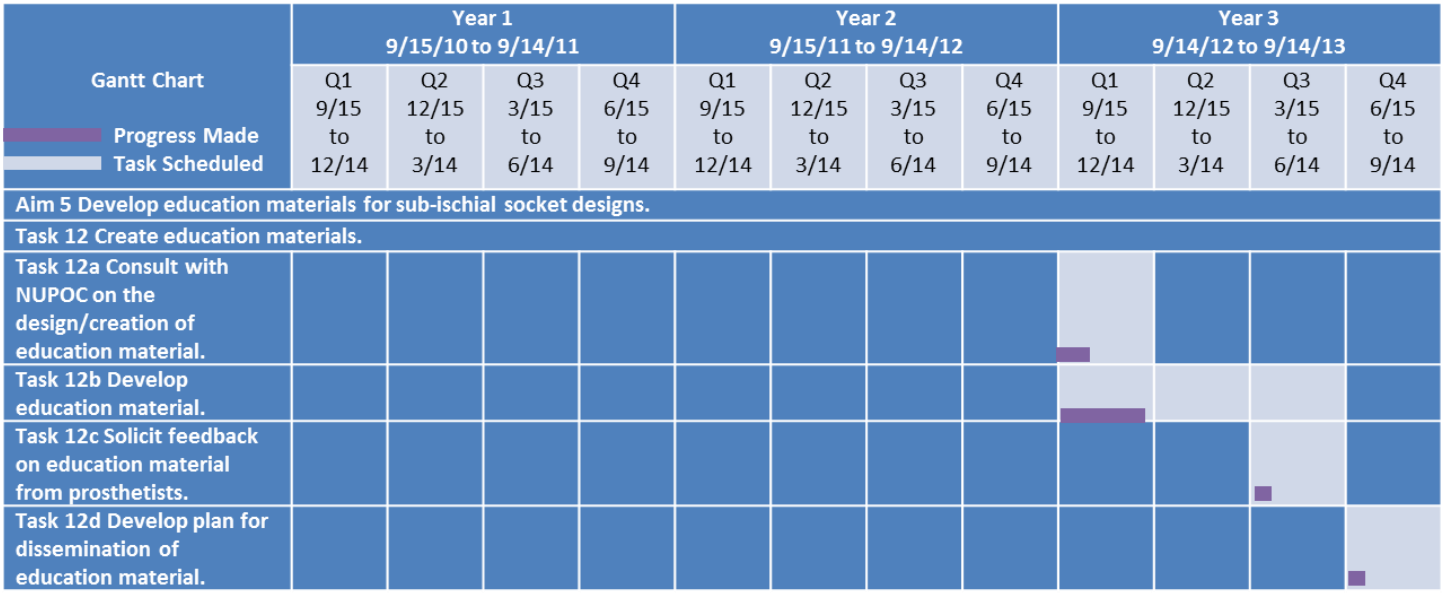


Figure 14 Effects of displacement mapping. The unmodified shape (left) shows no separation between its original mesh and the underlying shape, but the modified shape (right) shows an obvious separation. This was accomplished solely by applying the grayscale map. These maps can serve as templates for later use.

Task 12 Create education materials



Task 12a Consult with NUPOC on the design/creation of education material: *This task is in progress.* We have begun filming the casting, rectification, and fitting procedures for our sub-ischial socket. These videos will form part of an instructional manual that will support dissemination of the socket to other prosthetists. Plans are in place to edit these clips, record narration and film additional socket lamination procedures.

Task 12b Develop education material: *This task is in progress.* Educational material has been developed and shared with our colleagues at BAMC (see Task 9a) and education modules were developed and taught to the Northwestern University prosthetics students (see Task 12a). A second draft of our instructional manual incorporating videos has been prepared and is being shared with collaborators at BAMC for additional feedback.

Task 12c Solicit feedback on education material from prosthetists: *This task is in progress.* We received feedback from our colleagues at BAMC on the first draft of an instructional manual. After incorporating their comments, we have developed a second draft which is being shared with our colleagues at BAMC for feedback (see Task 9a and 12b).

Task 12d Develop plan for dissemination of education material: *This task is in progress.* Our application for an instructional course was accepted for presentation at the 2013 World Congress of the International Society for Prosthetics and Orthotics (Appendix A). Additionally, Ryan Caldwell spoke about vacuum-assisted technology at the 2012 meeting of the Midwest Chapter of the American Academy of Orthotists and Prosthetists.

Task 13 Final project meeting

Gantt Chart Progress Made Task Scheduled	Year 1 9/15/10 to 9/14/11				Year 2 9/15/11 to 9/14/12				Year 3 9/14/12 to 9/14/13			
	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14	Q1 9/15 to 12/14	Q2 12/15 to 3/14	Q3 3/15 to 6/14	Q4 6/15 to 9/14
Aim 5 Develop education materials for sub-ischial socket designs.												
Task 13 Final project meeting												
Task 13a Convene final project meeting.												

Task 13a Convene final project meeting: *Not scheduled to start.*

KEY RESEARCH ACCOMPLISHMENTS

- Completed the finite element model of a transfemoral sub-ischial prosthetic socket that can be used to analytically evaluate the performance of different frame designs using the socket-residual limb interface stress magnitude and distribution.
- Filed U.S. and PCT (foreign) patent application titled “Vacuum pump systems for prosthetic limbs and methods of using same.”
- Manuscript characterizing pump performance prepared for publication.
- Completed development of a computer program to quantify socket rectifications.
- Prepared second draft of an instructional manual incorporating videos, revised reductions algorithm and a sub-ischial socket measurement form.

REPORTABLE OUTCOMES

Abstracts	**Presented at the 38th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium to be held March 21-24, 2012, Atlanta, GA:** (1) Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum Assisted Suspension. (2) Socket/Liner Interface Volume and Vacuum Pressure Decay in Persons with Transfemoral Amputations. (3) Stress Analysis of Different Rigid Frame Designs of within a Flexible Transfemoral Prosthetic Socket.	Abstracts were submitted with Year 1 annual report
	Presented at the Military Health System Research Symposium, August 13-16, 2012, Fort Lauderdale, Florida: Quantification of Transfemoral Prosthetic Socket Fabrication (Poster).	**Appendix A**
	Accepted for presentation at the World Congress of the International Society for Prosthetics and Orthotics to be held February 4-7, 2013, Hyderabad, India: (1) Stress Analysis of Different Rigid Frame Designs with a Flexible Transfemoral Prosthetic Socket (Oral Presentation). (2) Socket/Liner Interface Volume and Vacuum Pressure Decay in Persons with Transfemoral Amputations (Oral Presentation). (3) Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum-Assisted Suspension (Poster). (4) Subischial Sockets with Vacuum Assisted Suspension for Persons with Transfemoral Amputation (Instructional Course).	**Appendix B**
	Accepted for presentation at the 39th American Academy of Orthotists and Prosthetists Annual Meeting and Scientific Symposium to be held February 20-23, Orlando, Florida: (1) An analytic approach to assessing transfemoral socket flexibility (Oral Presentation). (2) Role of socket design, flexibility and suspension in transfemoral sockets during walking (Poster).	**Appendix C**
Presentations	**Invited to present at the Design of Medical Devices Conference, April 10-12, Minneapolis, Minnesota:** Sub-ischial Prosthetic Socket with Vacuum-Assisted Suspension for Persons with Transfemoral Amputation.	
	Invited to present at the Midwest Chapter meeting of the American Academy of Orthotists and Prosthetists, September 27-29, Lake Geneva, Wisconsin: (1) Stress Analysis of Different Rigid Frame Designs within a Flexible Transfemoral Prosthetic Socket. (2) Subischial Socket Technology: Transfemoral Vacuum Concepts and Case Studies.	
Patent	Filed U.S. patent application titled “Vacuum pump systems for prosthetic limbs and methods of using same.” We also filed a PCT patent application.	
Funding	Applied for supplemental funding via the FY12 Joint Warfighter Medical Research Program to build and evaluate the proposed hybrid pump design.	

CONCLUSIONS

Aims 1 & 2: Results from our finite element model had shown a qualitative sensitivity to frame design with different global, non-uniform interface stress (pressure) distribution for each frame design tested, suggesting this approach (i.e. the finite element method) had the potential for use as a tool for assessment of flexible sockets. To quantify prosthetic socket flexibility, assessment regions based on clinically guided definitions of functional areas, were identified and analyzed. The analyses confirm earlier results and additionally, demonstrate regional variations in flexibility that are sensitive to frame design and thickness. Work is ongoing to incorporate more prosthetic socket loading scenarios in the computational model, with the goal of a more comprehensive simulation of socket performance at physiological loads reflective of a range of activity levels.

Regarding liner durability, we have noted liners are lasting longer since using Polytol material for the sub-ischial sockets and the Medi liner. There is significantly less abrasion of the reflected material compared to our experience with other laminations. We continue to explore issues of liner durability.

Aim 3: Repeat testing of the mechanical pumps with the MTS machine confirmed results of initial tests using a hand actuated lever, allowing us to more confidently move forward with preparation of a manuscript for publication, which is almost ready for submission.

Aim 5: The quantification program has been successfully used in the creation of color coded 3D educational models, see Figure 13. These models will be used to teach other prosthetists the rectification patterns used for different limb shapes. These models can also be used in the creation of templates for use in computer-aided socket design software.

REFERENCES

1. Gerschutz, M. J., M. L. Haynes, et al. (2012). "Strength evaluation of prosthetic check sockets, copolymer sockets, and definitive laminated sockets." J Rehabil Res Dev 49(3):405-426.
2. Wood, S.M. (2011). “Characterization and Design of Vacuum Pumps for Persons with Transfemoral Amputations.” Master of Science Thesis, Northwestern University, Evanston IL.

APPENDICES

A Poster, 2012 Military Health System Research Symposium

B Abstracts, 2013 World Congress of the International Society for Prosthetics and Orthotics

C Abstracts, 2013 39th American Academy of Orthotists and Prosthetists annual meeting

D Experimental Protocol for Tasks 4d and 4e

E Gait Analysis Results

F Overview of digitized shapes

Appendix A

MHSRS-12-143

Military Health System Research Symposium, Ft. Lauderdale, August 13-16, 2012

Quantification of Transfemoral Prosthetic Socket Fabrication

Oluseeni Komolafe, PhD, Kerice Tucker, Ryan Caldwell, CP, Stefania Fatone, PhD, BPO(Hons)

Northwestern University Prosthetics-Orthotics Center (NUPOC)

NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE

NORTHWESTERN UNIVERSITY

Background

Prosthetic socket fabrication is typically a specialized process heavily dependent on the craftsmanship skill of the prosthetist. Efficient knowledge dissemination and automation of the fabrication process requires quantification of this process.

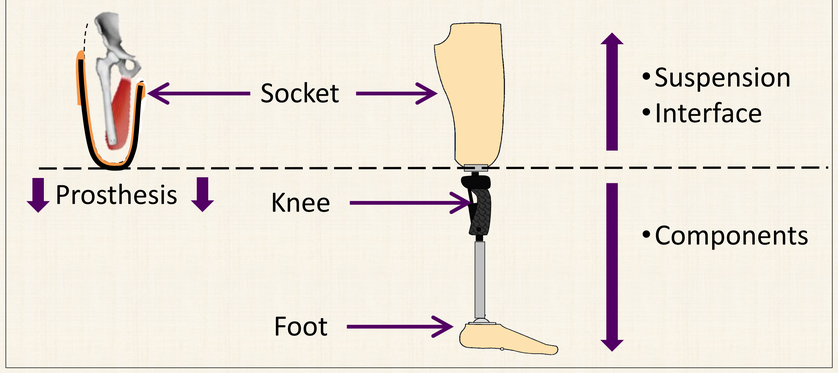
Purpose of the Study

To quantify the specialized process of fabricating sockets for highly active persons with transfemoral amputations (TFA).

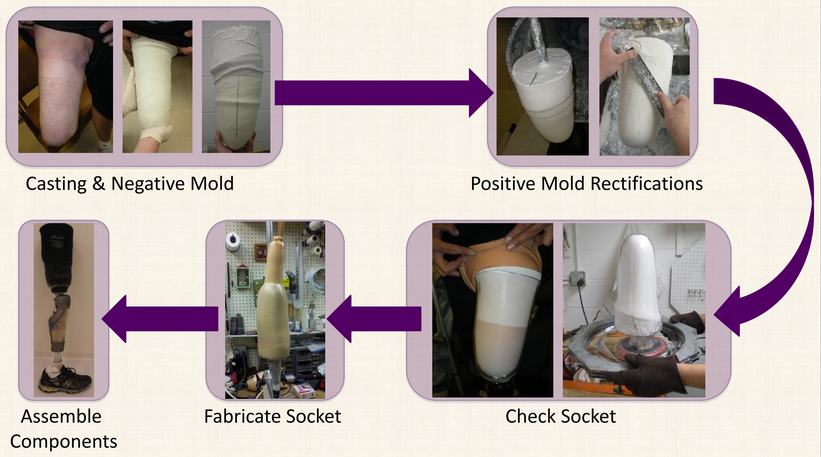
A. Quantify clinical (pre- and post) rectifications
B. Quantify the socket (frame) development process

Introduction

Transfemoral Prosthesis Orientation



Typical Transfemoral Socket Fabrication Process



Observations

- Process is time and resource intensive
- Heavy dependence on clinician experience and craftsmanship
- High variability of quality outcomes
- Process is difficult to quantify and effective instruction typically requires a one-to-one "apprentice" model

Relevance to Military Medical Care

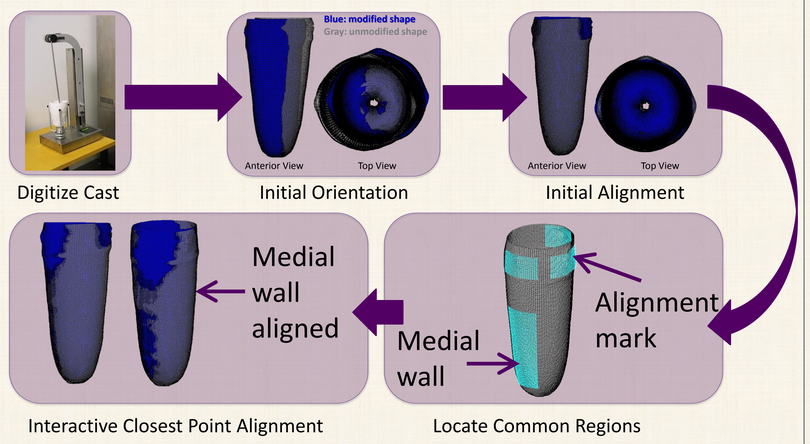
- Prevalence (TFA): General 20% (Owings, 1998); Military 31% (Stansbury, 2008)
- Service persons with amputations
  - Generally young and extensively trained
  - Have high expectations of their function with prostheses

Novel Sub-Ischial Transfemoral Socket

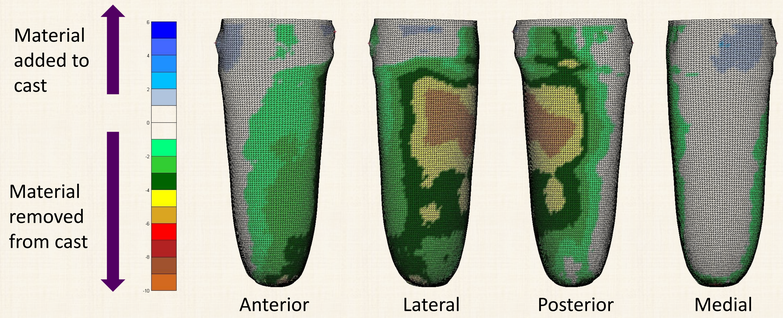
- Vacuum assisted suspension
- Lower sub-ischial proximal trimlines
- 4-Stage lamination procedure
- Optimized frame geometry to increase socket flexibility

Methods/Results

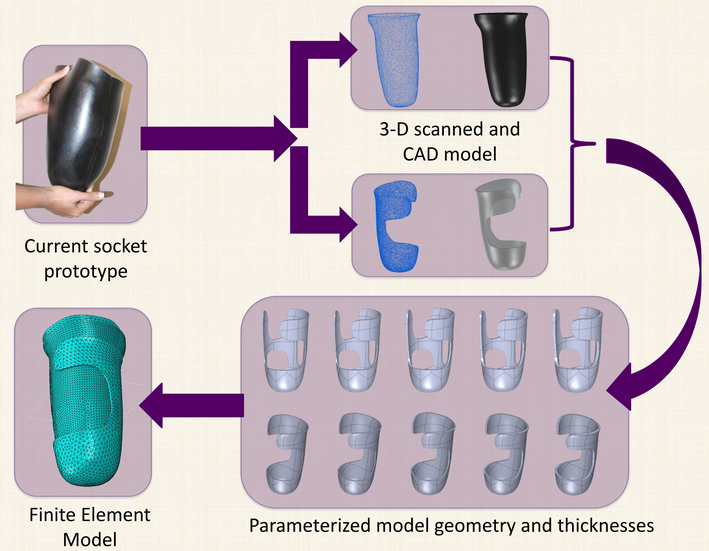
A. Quantifying Clinical (Pre- and Post) Rectifications



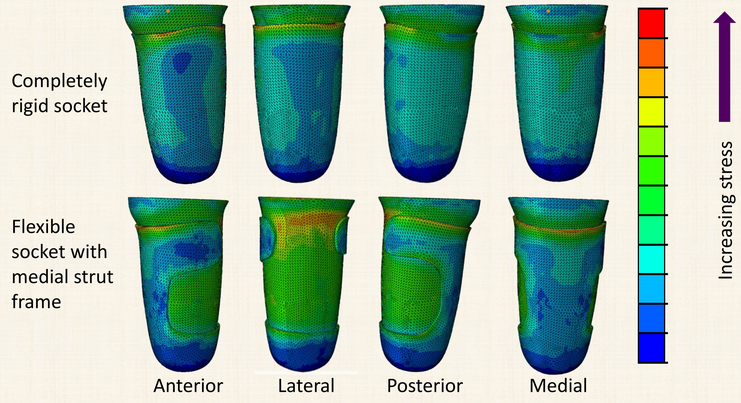
Results: Rectification Patterns



B. Quantifying the Socket (Frame) Development Process



Results: Stress Distribution Patterns



Conclusions

The majority of the rectifications are in the proximal lateral portion of the cast. Preliminary results demonstrate that different frame geometries have different effects on the socket stress distribution.

Implications/Applications

- Technology assisted fabrication (CADCAM, rapid prototyping, etc.)
- Facilitates knowledge dissemination of specialized techniques

Funding Acknowledgement

Award #W81XWH-10-1-0744

The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702-5014 is the awarding and administering acquisition office. The content of this presentation does not necessarily reflect the position or the policy of the Government, and no official endorsement should be inferred.

Appendix B

Title – Stress Analysis of Different Rigid Frame Designs with a Flexible Transfemoral Prosthetic Socket

Introduction

In vacuum suspension sockets, loss of elevated vacuum pressure is often a result of non-conformation of the socket material to changes in residual limb shape and volume. Reduced vacuum suspension may lead to increased relative movements (i.e. pistoning) of the residual limb within the socket. Fabrication of the socket from a flexible material provides a direct solution; however, to be of practical use, minimum socket rigidity for stable load transfer between the residual limb and prosthesis must be maintained. To maximize socket flexibility, we use a fenestrated rigid socket (i.e. frame) embedded within a laminated polyurethane flexible material. We present results of a finite element (FE) analysis evaluating the effect of different frame designs on residual limb/socket interface stress distributions.

Methods

Equipment: Creaform 3-D digitizer, Novel pliance system, Instron mechanical testing system

Procedure: A FE model of a transfemoral sub-ischial prosthetic socket is developed and validated. The model assembly was simplified to the following components: (1) Rigid frame, (2) Flexible polyurethane layer, (3) Silicone liner and (4) Residual limb. A FE analysis was then performed in Abaqus FEA (Dassault Systemes).

Results

Qualitative results from the FE analysis showed a non-uniform stress distribution that was different for each socket. Preliminary results indicate regions of high normal stresses around the proximal brim and regions of low normal stress values along the lateral wall of the socket. On-going work is focused on quantitative assessment of the effect of different frame geometries of various thicknesses on the stress distribution.

Discussion

The sockets differed only in locations and extent of cut-outs within their rigid frames. Cut-outs in transfemoral sockets have been used to provide release areas that accommodate displaced tissues. The results suggest this approach is useful to optimize flexible sockets capable of conforming to changing residual limbs, while achieving biomechanical load requirements.

Title – Characterization of Mechanical and Electrical Vacuum Pumps for Use in Vacuum-Assisted Suspension

Introduction

Vacuum-assisted suspension is becoming a popular system for use in lower-limb prostheses. However, the performance of current prosthetic vacuum pumps has not been studied. In this study, prosthetic vacuum pumps, both mechanical and electrical, were tested and compared to gain insight into their overall performance and efficiency.

Methods

We compared 2 electrical (Otto Bock Harmony® epulse and Ohio WillowWood LimbLogic® VS) and 3 mechanical pumps (Otto Bock Harmony® P3, P2, and HD). Sealed canisters simulated estimated volumes of a range of socket/liner interfaces (37.5, 68.6, 99.3, 133.1, 198.9 cm3). A lever activated fixture was used to actuate the mechanical pumps. Each canister was evacuated to ~17 inHg at least 5 times with each pump. Vacuum pressure and time were recorded during evacuations using a digital gauge. Electrical pumps were also tested repeatedly on the 99.3 cm3 canister to complete battery depletion. All P3 functional rings (f0 to f4) were tested, while the P2 and HD pumps were set for a 55 kg patient (equivalent to the P3 f0 ring). Average power was calculated by multiplying the achieved vacuum pressure by the canister volume and dividing by the time taken to achieve that pressure.

Results

The LimbLogic® was 47% more powerful on average than the e-pulse. There was a large difference in number of evacuations to complete battery depletion between electrical pumps (e-pulse < 180 trials; LimbLogic® > 225 trials). Additionally, time to evacuation for the epulse increased by 7.5% over the course of battery depletion, while the LimbLogic® demonstrated no change. The P3 was the most “powerful” of the mechanical pumps.

Discussion/Conclusion

While this study provides some insight into pump performance it may not be directly indicative of in-vivo performance given other prosthetic and human subject variables that may affect development and maintenance of vacuum.

Title – Socket/Liner Interface Volume and Vacuum Pressure Decay in Persons with Transfemoral Amputations

Introduction

Vacuum-assisted suspension (VAS) is becoming a popular system for use in lower-limb prostheses. However, little is known about socket/liner interface volume in persons with transfemoral amputations (TFA) or the rate of vacuum pressure decay during regular activity. We measured changes in vacuum pump pressures on human subjects, empirically obtaining evacuation curves and gaining insights into volume and pressure decay.

Methods

Persons with unilateral TFA using VAS, sub-ischial sockets and silicone liners participated. Otto Bock Harmony® e-pulse and Ohio WillowWood LimbLogic® VS pumps were tested. Each subject donned their prosthesis and stood quietly while the space between socket and liner was evacuated to ~17 inHg (5 evacuation trials per pump). Between trials, air was allowed into the system by disconnecting the tubing attaching pump to socket. Vacuum pressure data and time were recorded during evacuation using a digital gauge. Some subjects also walked for 10 minutes with each pump at a comfortable pace on a treadmill while vacuum pressure was monitored. Interface volume was calculated from the relationship between time to evacuation in the human subjects and time to evacuate sealed canisters of known volume which were assessed for the same pumps.

Results

Twelve subjects (age = 56±14 years; height = 174±7cm; mass = 82±25kg) were tested. Calculated average interface volume was 97.8±47.4cm3 and 103.3±49.2cm3 for the e-pulse and LimbLogic, respectively. During treadmill walking (4 subjects) the average rate of vacuum decay was 0.0045 ± 0.0021 and 0.0061 ± 0.0047 inHg/sec for the e-pulse and LimbLogic, respectively. Evacuation curves for some human subjects differed in shape from those of fixed volume canisters, resembling s-shaped curves.

Discussion/Conclusion

S-shaped curves may represent a change in the initial volume for those people with “soft” tissue who are pulled into the socket by vacuum. Testing on a greater number of subjects is needed.

Appendix C

AN ANALYTIC APPROACH TO ASSESSING TRANSFEMORAL SOCKET FLEXIBILITY

OA Komolafe, R Caldwell, S Fatone
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INTRODUCTION

Flexible prosthetic socket systems are generally thought to contribute positively to residual limb health and comfort of persons with amputations. Such systems allow greater accommodation of the socket walls to muscular contraction, improving circulation, as well as improving suction suspension due to the clinging nature of the socket walls (Pritham, 1985). Early examples of flexible systems include the use of double wall sockets, with a flexible inner socket joined to an outer rigid socket (McCollough, 1968) and a decade later, fenestrated sockets, with supporting struts formed by windows cut into the rigid socket at medial, posterior and anterior locations (Volkert, 1982). However, despite continued development of such flexible socket systems, there remains a need for formalization of the criteria defining socket flexibility. Existing working definitions, such as that articulated by Ossur Kristinsson as *"the ability to deform* [the socket] *by hand and the resistance to stretching under the loads it will be subject to,"* although accurate, are not sufficiently nuanced to allow comparison of dissimilar flexible socket designs. The goal of this work was to use an analytic process to provide guidelines for characterization of transfemoral socket flexibility, incorporating the following elements:

(1) Identification of regions of the socket that have distinct functions of clinical significance;
(2) An analytic evaluation of the deformation and internal socket stresses at these functional regions using a computational model.

METHOD

Apparatus: 3-D Creaform Megacapturor digitizer, Abaqus (Dessault Systemes), AMTI forceplates.

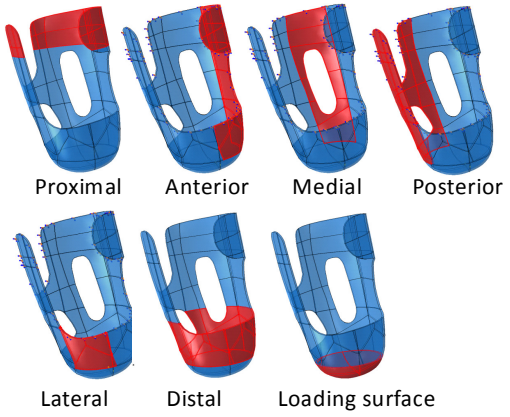

Figure 2: Selected functional regions on the structural frame component of a sub-ischial transfemoral socket.

Procedure: (A) Distinct regions of a transfemoral prosthetic socket with different loading and support functions were identified through discussion with an experienced Certified Prosthetist (Fig 1). (B) The selected regions were evaluated in a previously described finite element model of a sub-ischial prosthetic socket (Komolafe et al. 2012). Evaluation included a global deformation and stress assessment of the selected "functional regions" (from A above).

Data Analysis: The equivalent (von Mises) stress was calculated as an average of all elements in the selected region.

RESULTS

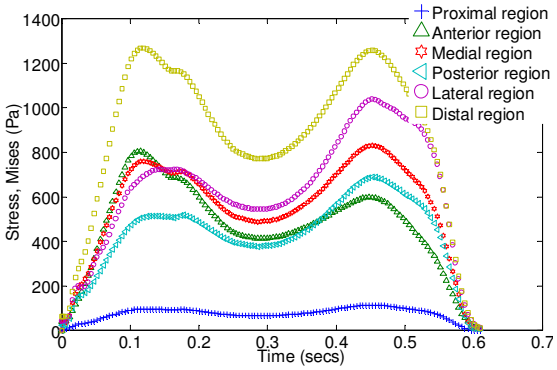

Figure 1: Results from computational model of sub-ischial socket subjected to experimentally measured stance loads.

DISCUSSION/CONCLUSION

Our analysis (Fig 2) confirmed the region of maximum socket flexibility (indicated by minimum stress values) for the duration of the stance phase in this sub-ischial socket design was along the proximal brim. During loading response and early stance, calculations indicated low deformation (and high stresses) along the anterior and medial regions, however, during later stance; low values of deformation were calculated along the posterior and lateral regions of the socket.

CLINICAL APPLICATIONS

Characterization of regional socket flexibility for different loading conditions may benefit the design of activity specific socket systems.

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February 20-23, 2013

Role of socket design, flexibility and suspension in transfemoral sockets during walking

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INTRODUCTION

Ischial Containment (IC) sockets encompass the pelvis and hip joint limiting hip range of motion and compromising comfort (Tranberg et al. 2011). With the advent of vacuum-assisted suspension (VAS) there has been an increasing interest in brimless sockets (Kahle 2002; Fairley 2008; Strachan et al. 2011; Kahle & Highsmith 2011, 2012). The purpose of this case study was to assess the role the brim and flexibility of the socket have on stability, comfort, suspension and gait parameters during walking.

METHOD

Subject: 29 year old male with a unilateral transfemoral amputation due to trauma (height 182cm; weight 83.3kg). Relatively long residual limb (48% of leg length) with average to firm skin tissue.

Apparatus: 8 camera motion analysis system (Motion Analysis Corporation) with 6 force plates (AMTI) embedded in the middle of a 12m walkway.

An IC socket with modified NU/RIC design, silicone seal-in suction suspension and one-way valve was used as the starting point (Fig 1). Socket was constructed of (1) a rigid carbon frame with posterior U-shaped fenestration and 1.5" Dacron strap over gluteal region; and (2) flexible thermoplastic inner socket with ½" flexible brim extending proximal to the carbon frame. Subject was assessed by a Certified Prosthetist as having total contact and appropriate containment in the socket. Prosthetic alignment was unchanged for conditions 1 to 6. Prosthetic components for all test conditions included a C-leg with torsion pylon (Otto Bock) and Highlander foot (Freedom Innovations).

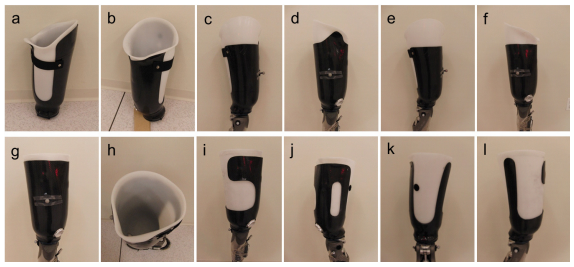

Figure 1. Viewing angle: Condition 1: (a) posterior lateral (b) posterior medial. Condition 2: (c) lateral (d) anterior. Condition 3: (e) lateral (f) anterior. Condition 4: (g) anterior (h) superior. Condition 5: (i) anterior (j) medial (k) posterior (l) lateral.

Procedures: Gait analysis was conducted on a single day. Subject walked at a comfortable self-selected speed in 7 socket conditions: (1) intact IC socket; (2) IC socket with lateral proximal frame removed; (3) IC socket with anterior medial frame removed; (4) brimless socket with rigid frame; (5) brimless socket with more flexible frame; (6) condition 5 with VAS (e-pulse, Otto Bock); (7) condition 6 with alignment adjustment.

Data Analysis: We recorded subjective comments, Socket Comfort Score (0 represents the most uncomfortable socket fit imaginable and 10 represents the most comfortable socket fit) (Hanspal et al. 2003), walking speed, stride width, and maximum lateral trunk lean in prosthetic stance for each socket condition.

RESULTS

Socket	SCS	Comment	Speed (m/s)	Step Width (cm)	Max Lateral Trunk Lean (degrees)
#1	2	Lots of pressure on IT	1.71	15.44	**2.6**
#2	2	Still pressure on IT	1.64	15.57	3.4
#3	5	Still pressure on IT but not as bad, alignment is off – toes are too in	1.65	**14.23**	4.3
#4	4	Socket more comfortable but foot feels too far back	1.69	15.13	4.0
#5	2	Socket feels like it wants to come off	1.63	17.94	3.2
#6	4	Way better, rotational wobble gone	1.71	14.98	3.3
#7	**6**	That's more like it!	**1.84**	16.3	3.7

Table 1. Results for conditions #1 to #7. Bold indicates "best" result for each variable, underline indicates the "worst" result. IT = ischial tuberosity. SCS = socket comfort score.

DISCUSSION/CONCLUSION

Subjective comments and data did not match exactly. No one condition clearly provided the greatest comfort, fastest speed, smallest step width and least coronal plane trunk motion for this subject. However, removing the lateral and medial walls affected stability as suggested by increased lateral trunk lean.

CLINICAL APPLICATIONS

Removing the brim of an IC socket appears to affect gait if VAS is not used.

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Appendix D

EXPERIMENT TO INVESTIGATE LINER FAILURE IN TRANSFEMORAL PROSTHETIC SOCKET APPLICATIONS

Northwestern University Prosthetic-Orthotics Center

Purpose:
To simulate conditions that are thought to be mainly responsible for ***liner failure*** of users of transfemoral prosthesis

Introduction
Interactions with users of prosthesis suggest the primary mode of failure is a knife edge action of the brim of the rigid socket through the side of the liner. This protocol explores this failure mode and compares the forces required to cut through a selected liner for different types of socket brims.

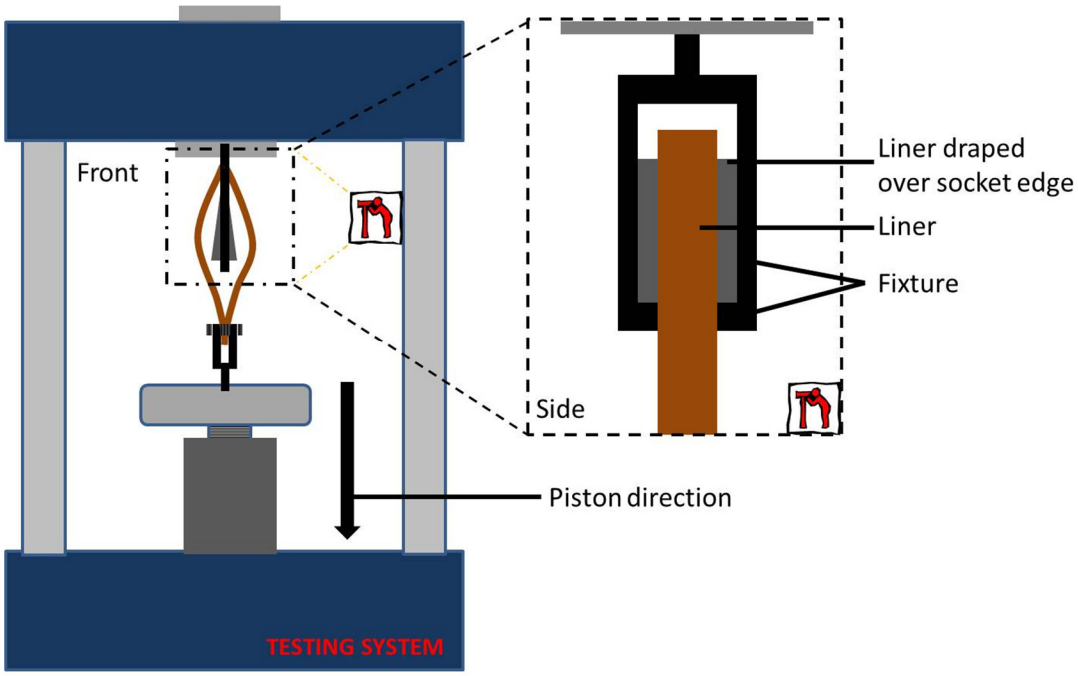
Equipment and Materials:
Loading system: Servo-hydraulic loading system (Inston™, Eden Prairie, MN)

Protocol:

Three different socket test specimens will be prepared and tested
1) Sanded carbon-fiber frame edge
2) Carbon-fiber frame covered with plastic edging finishing
3) Polytol edge

No. of Specimen: For each specimen of the socket material, test 3 liner trials

Schematic:



Recorded Measures:
1) Force
2) Displacement (strain)

Appendix E

Comparing Gait in Ischial Containment and SubIschial Sockets for 2 subjects

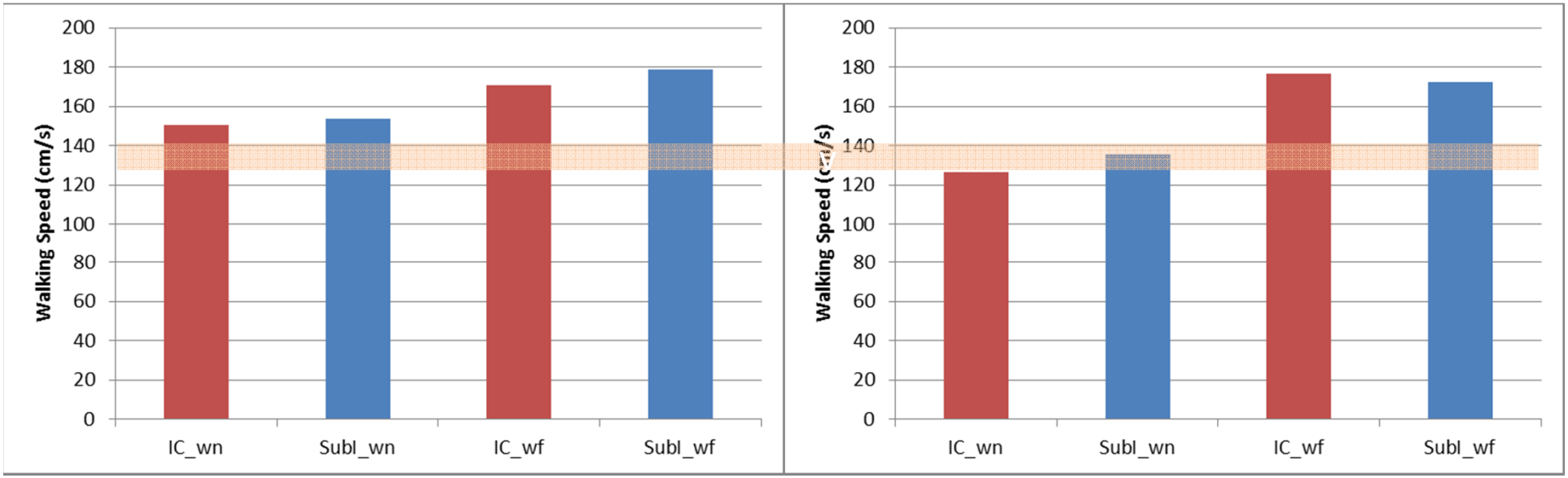
	Subject 1	Subject 2
Age	29	26
Sex	M	M
Height (cm)	181	188
Weight (kg)	84.4	89.6
Amputation	R TFA	L KDA
Cause of Amputation	Trauma	Tumor
Time since Amputation	9 years	15 years
Usual socket	Sub-Ischial	Ischial Containment
Usual suspension	Vacuum (Otto Bock e-pulse)	Suction one-way valve
Usual knee	C-leg (Otto Bock)	C-leg (Otto Bock)
Usual pylon	Torsion	Rigid
Usual foot	Highlander (Freedom Innovations)	Ceterus (Ossur)
Activity Level	Very active (construction worker)	Very active (athletic trainer)

	Subject 1		Subject 2	
Socket	Ischial Containment	Sub-Ischial	Ischial Containment	Sub-Ischial
Suspension	Suction one-way valve	Vacuum (Otto Bock e-pulse)	Suction one-way valve	Vacuum (Otto Bock e-pulse)
Knee	C-leg (Otto Bock)	C-leg (Otto Bock)	C-leg (Otto Bock)	C-leg (Otto Bock)
Pylon	Torsion	Torsion	Rigid	
Foot	Highlander (Freedom Innovations)	Highlander (Freedom Innovations)	Ceterus (Ossur)	Highlander (Freedom Innovations)
Socket Comfort Score				
Sitting	8	10	-	10
Standing	3.5	10	-	9
Walking	2	10	8	9

	Subject 1		Subject 2	
	Ischial Containment	Sub-ischial	Ischial Containment	Sub-Ischial
Rapid Sit to Stand	11.81	11.66	9.41	10.46
Four Square Step Test	9.52	10.6	5.47	6.95
Agility T Test	26.6	26.81	15.75	13.1

Walking Speed

Subject 1	Subject 2

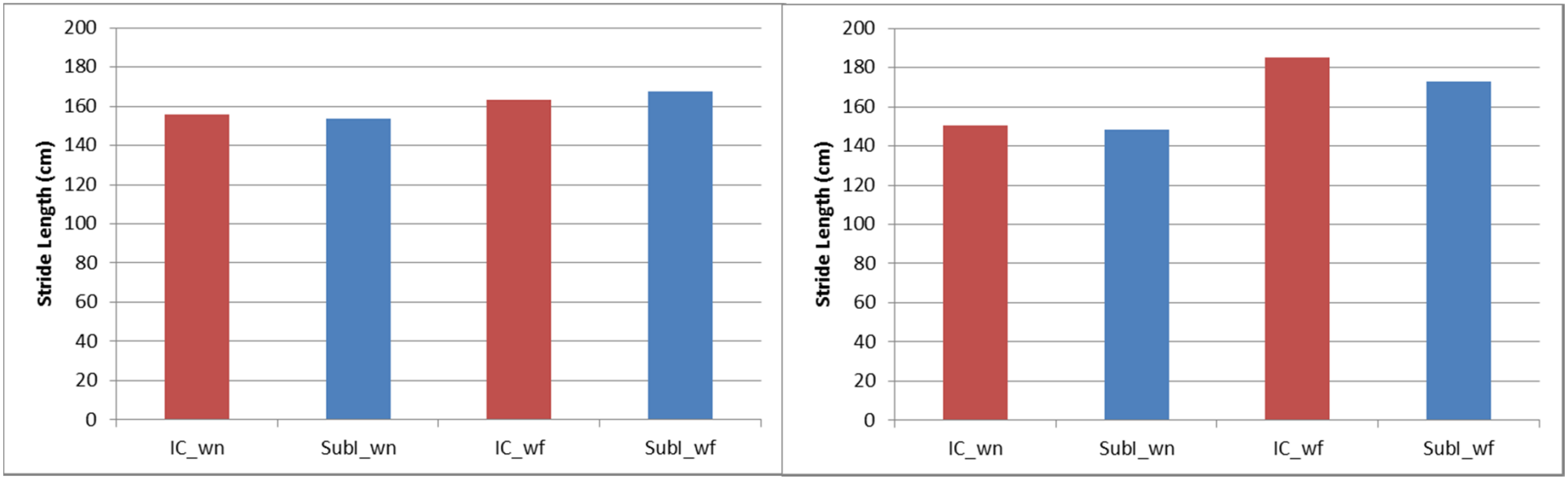


wn = self-selected normal walking speed
wf = self-selected fast walking speed

Able-bodied Reference

Stride Length

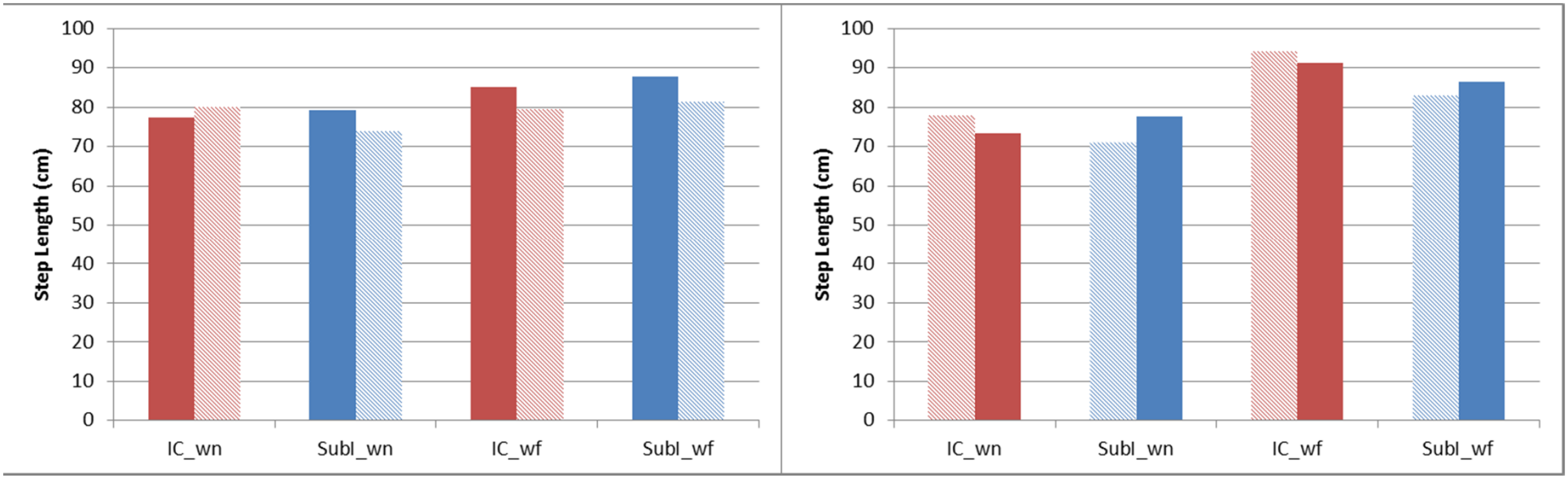
Subject 1	Subject 2



wn = self-selected normal walking speed
wf = self-selected fast walking speed

Step Length

Subject 1	Subject 2

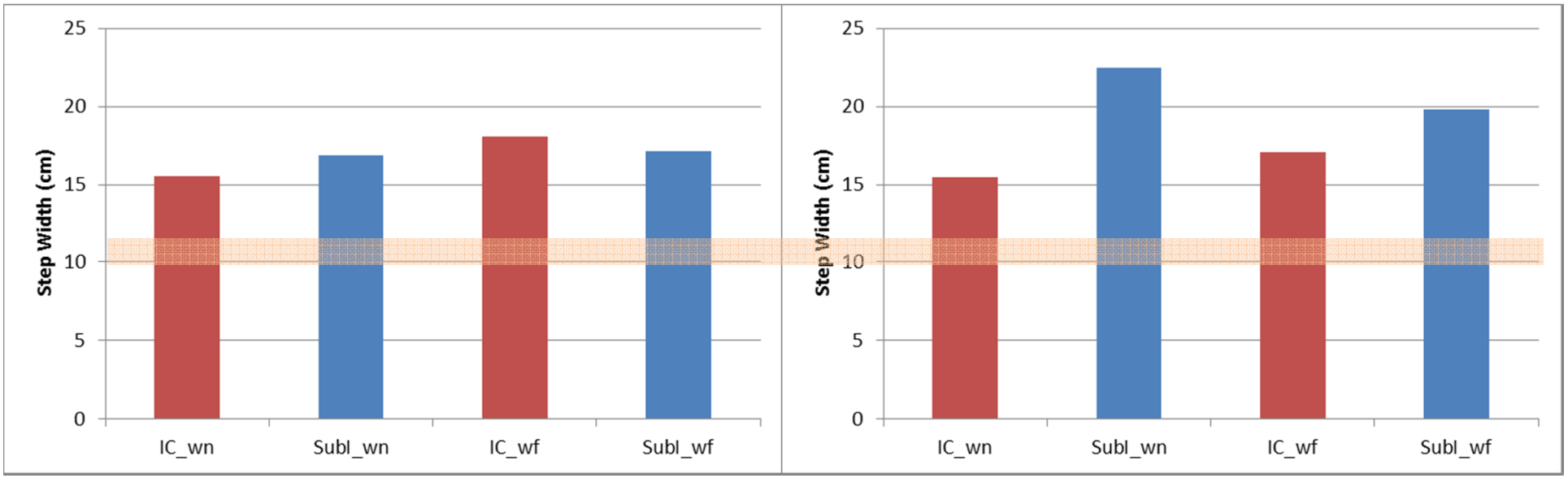


wn = self-selected normal walking speed
wf = self-selected fast walking speed

Prosthetic Side Sound Side

Step Width

Subject 1	Subject 2

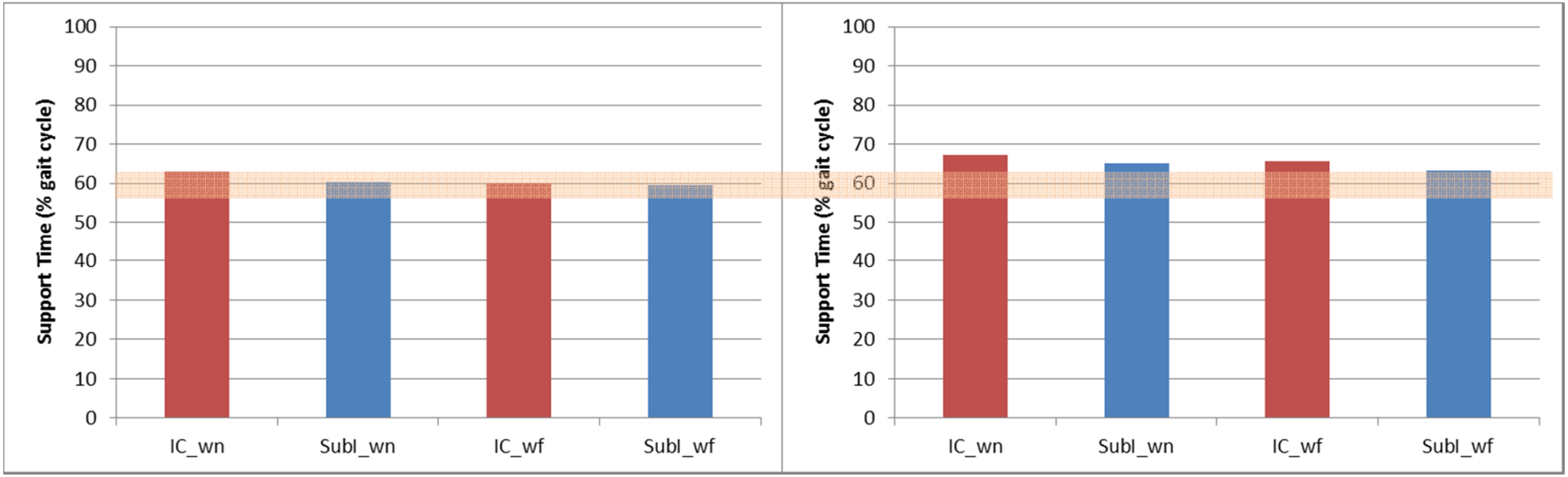


wn = self-selected normal walking speed
wf = self-selected fast walking speed

Able-bodied Reference

Stance Duration

Subject 1	Subject 2

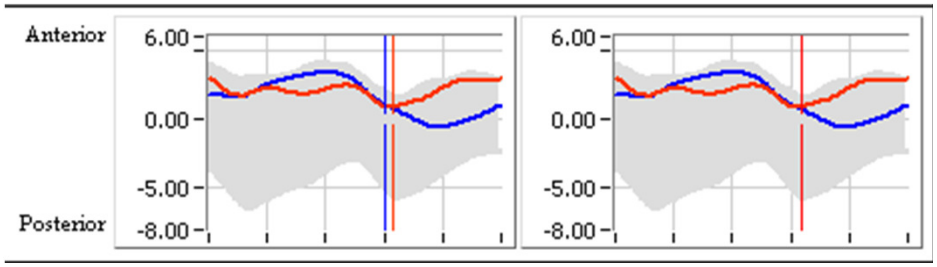


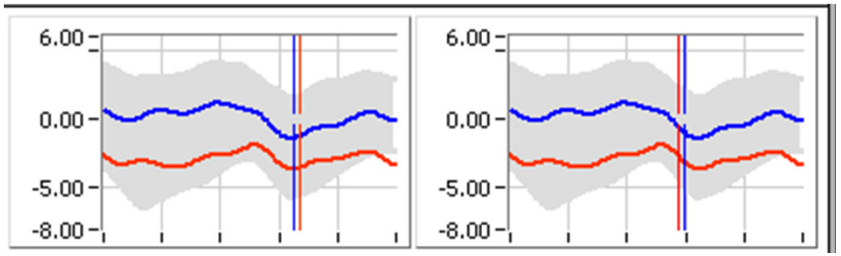
wn = self-selected normal walking speed
wf = self-selected fast walking speed

Able-bodied Reference

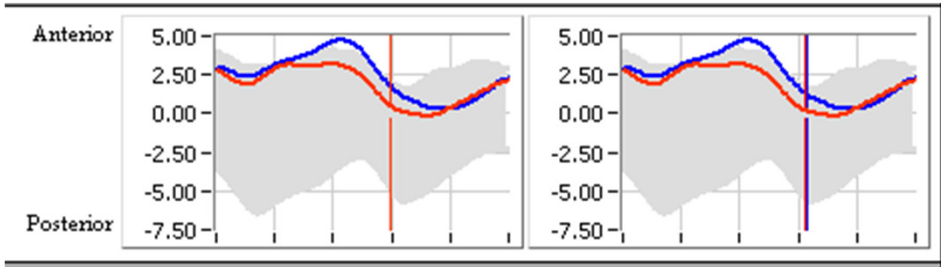
Trunk Tilt

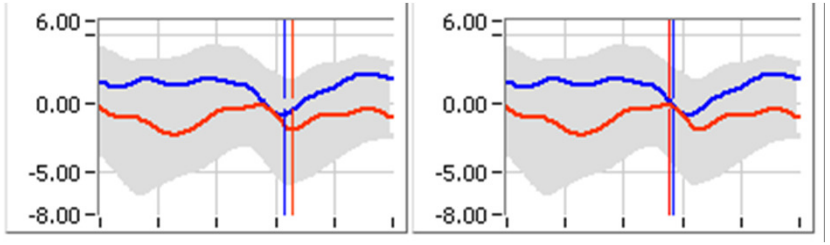
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

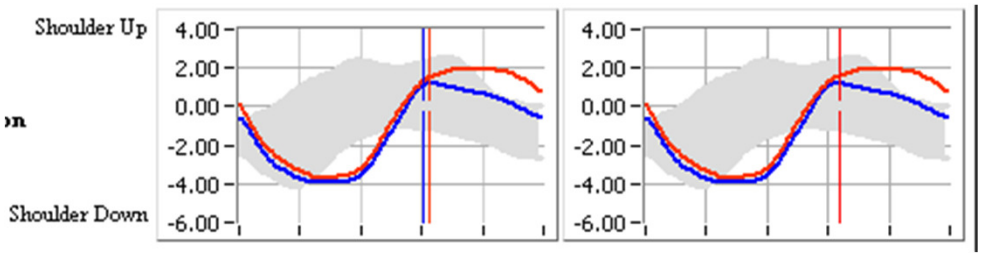


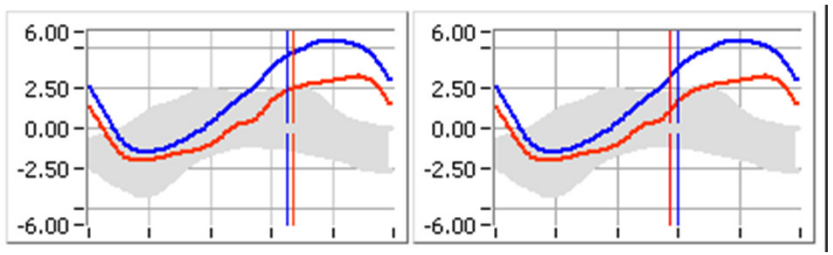


Ischial Containment Sub-Ischial

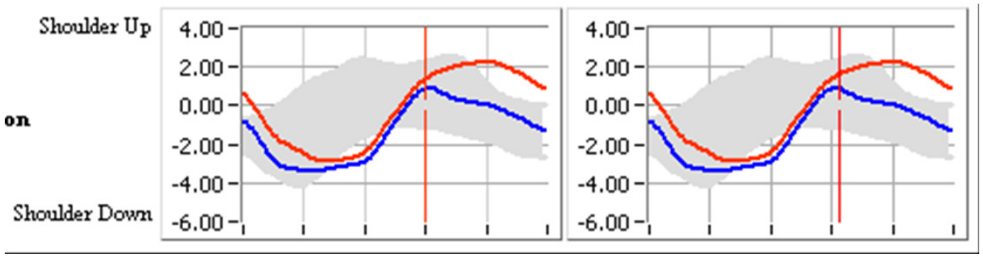
Lateral Trunk Lean

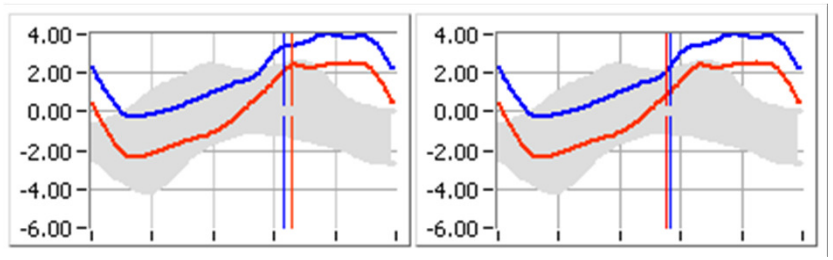
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

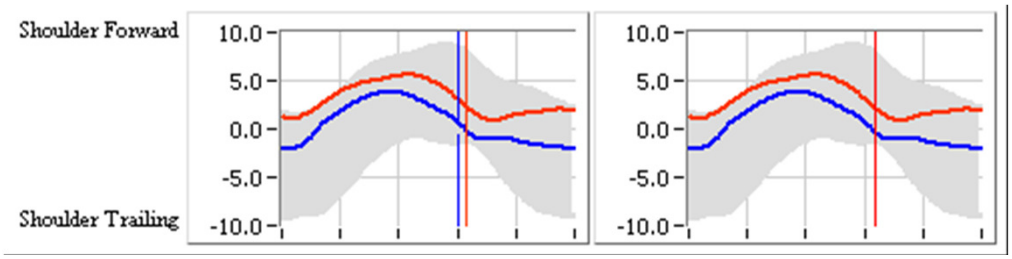


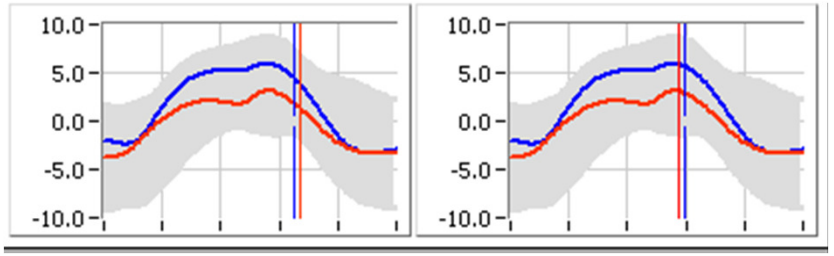


Ischial Containment Sub-Ischial

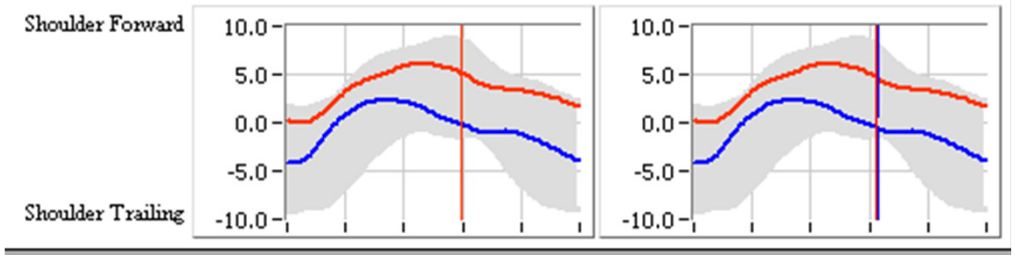
Trunk Rotation

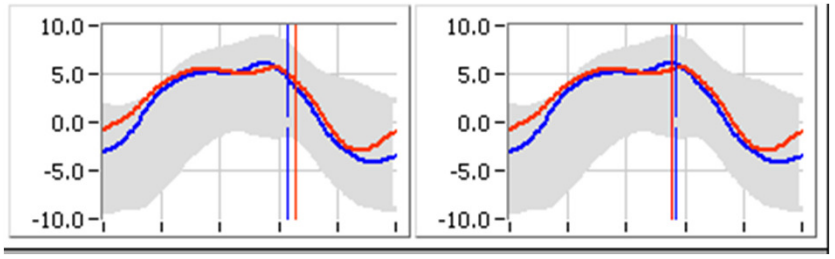
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





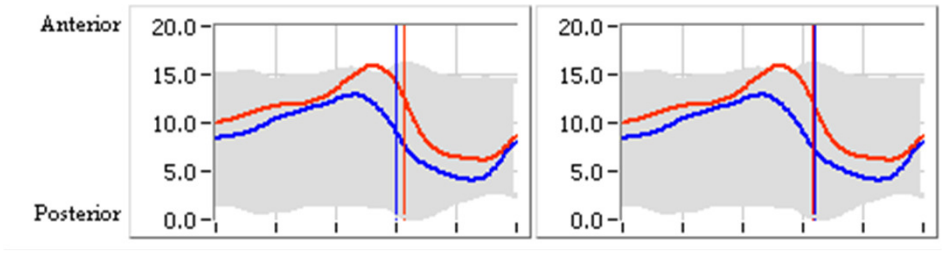
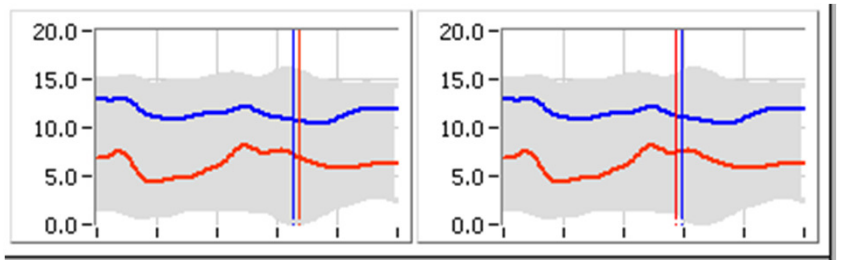
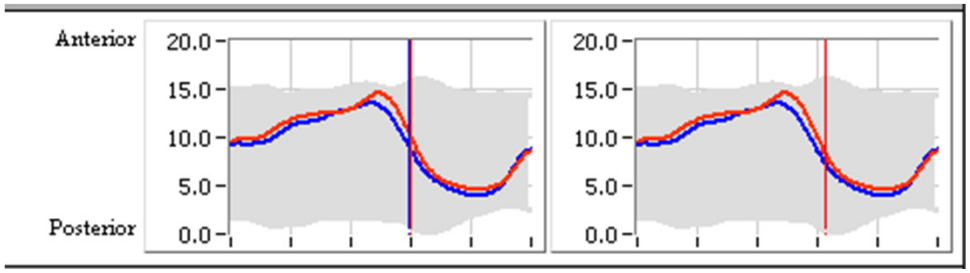
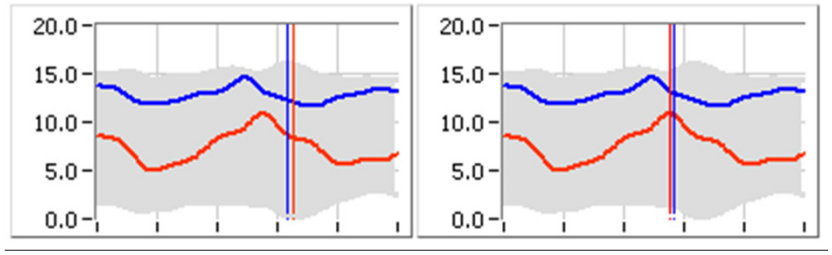
Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Ischial Containment Sub-Ischial

Pelvic Tilt

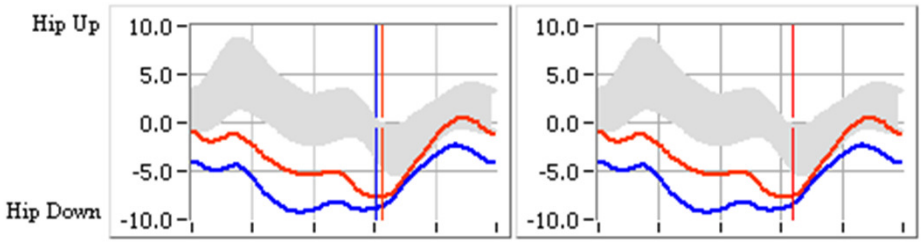
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic
			
Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic
			

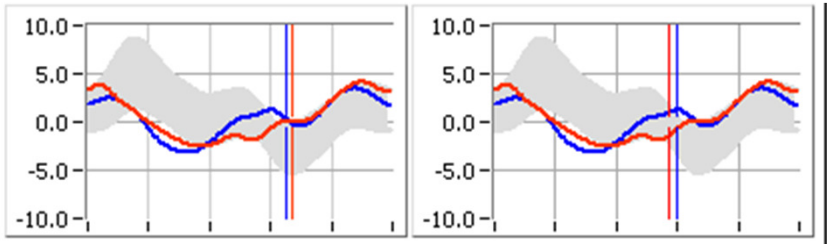
Ischial Containment

Sub-Ischial

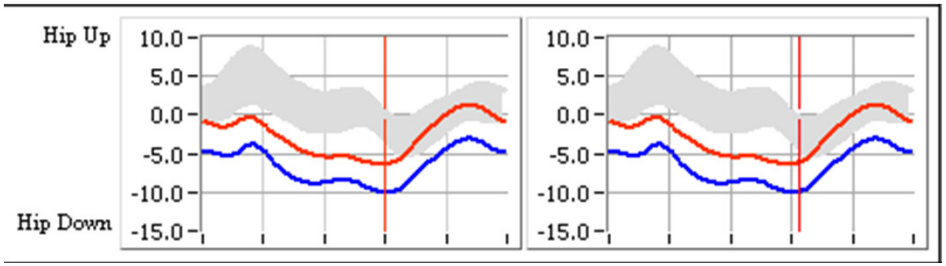
Pelvic Obliquity

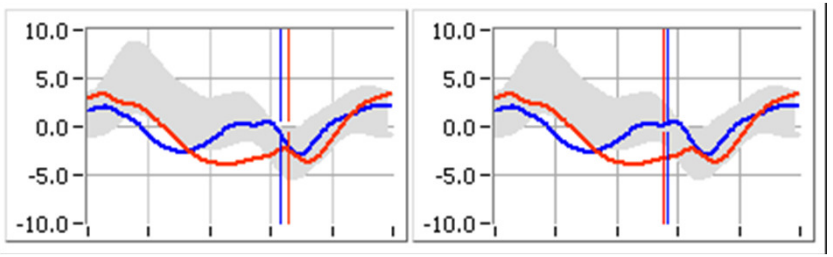
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



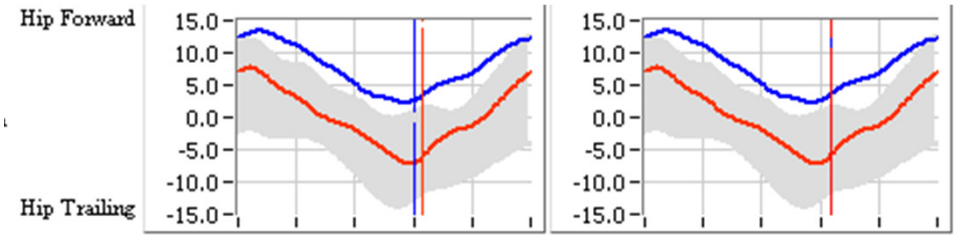


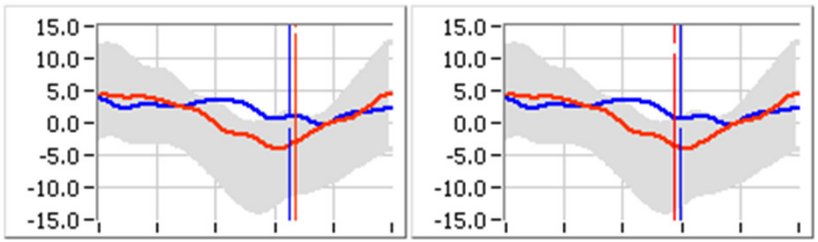
Ischial Containment

Sub-Ischial

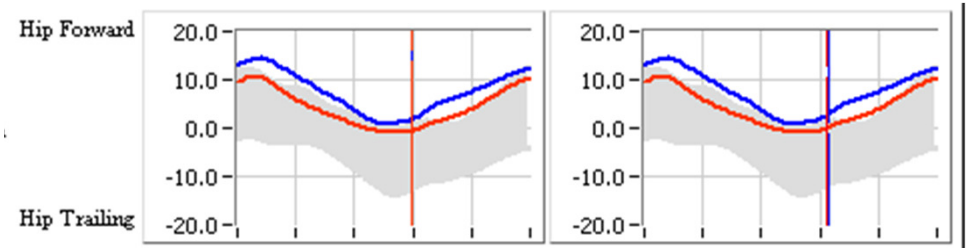
Pelvic Rotation

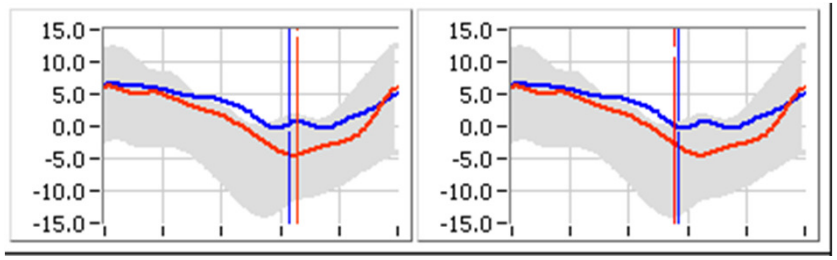
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



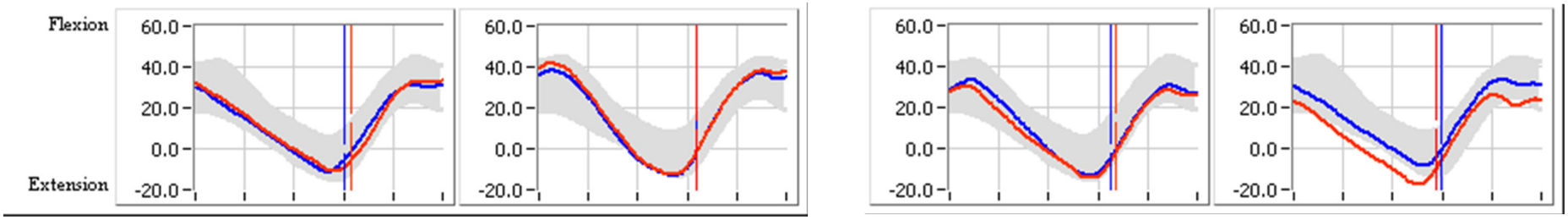


Ischial Containment

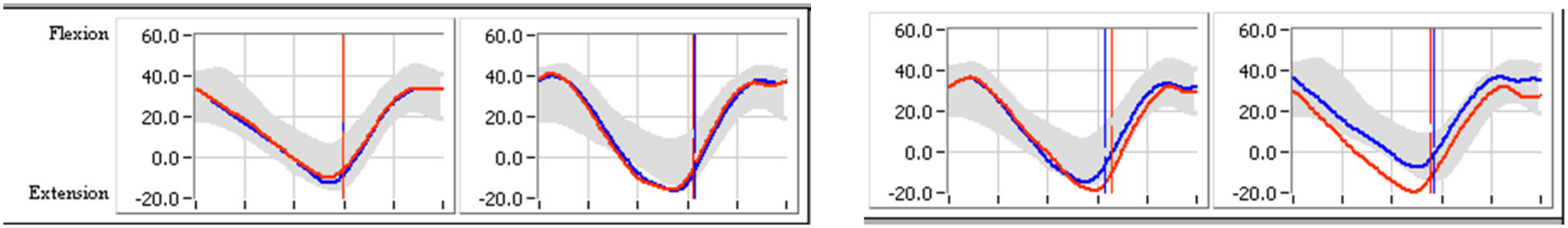
Sub-Ischial

Hip Flexion/Extension

Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

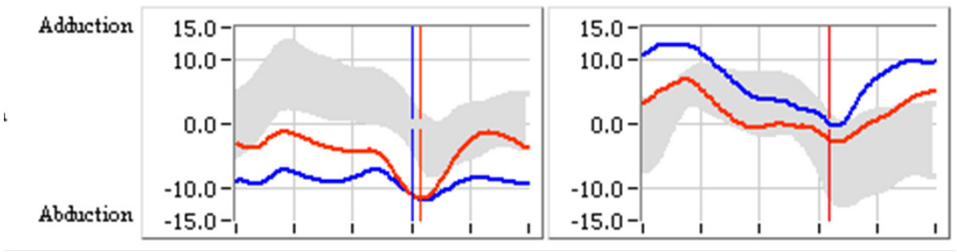


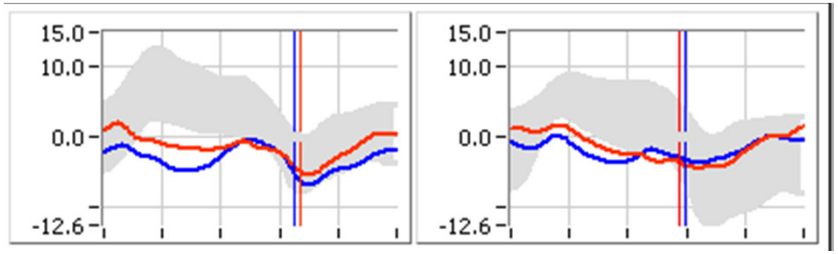
Ischial Containment

Sub-Ischial

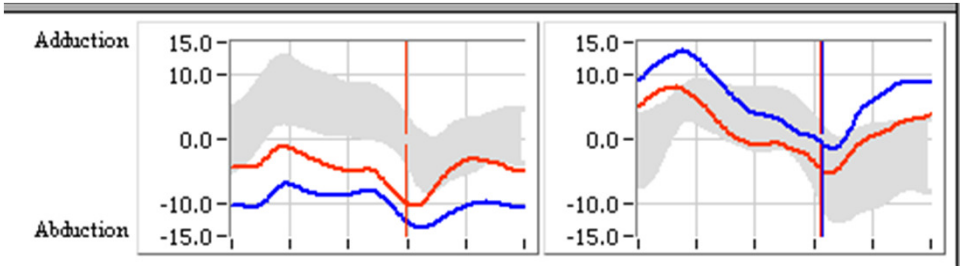
Hip Abduction/Adduction

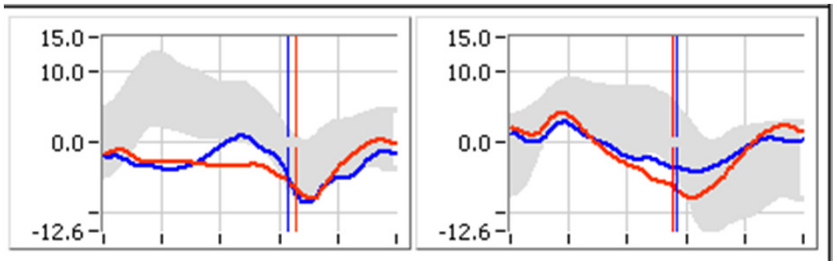
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



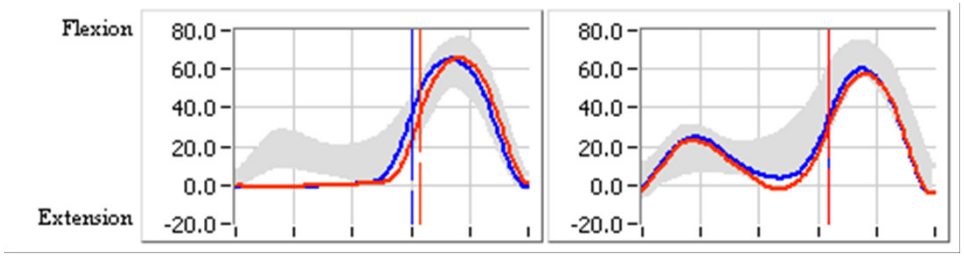


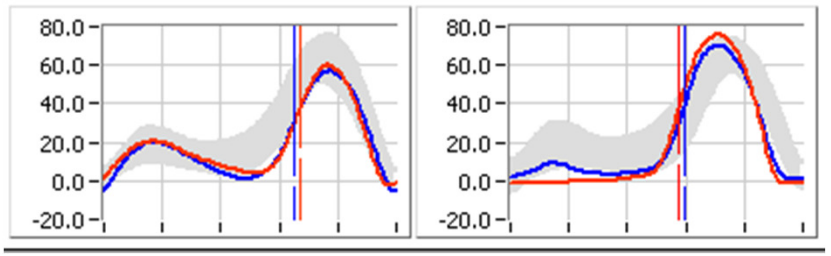
Ischial Containment

Sub-Ischial

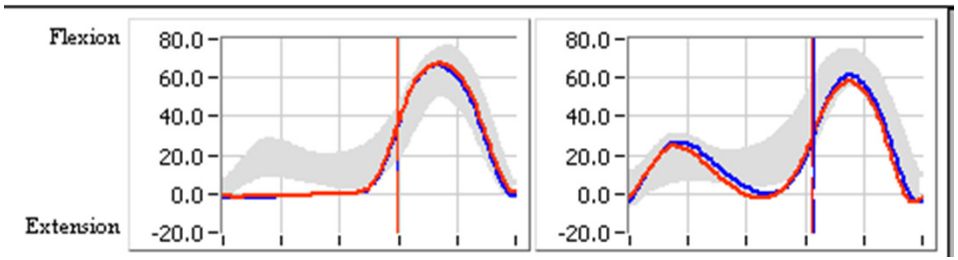
Knee Flexion/Extension

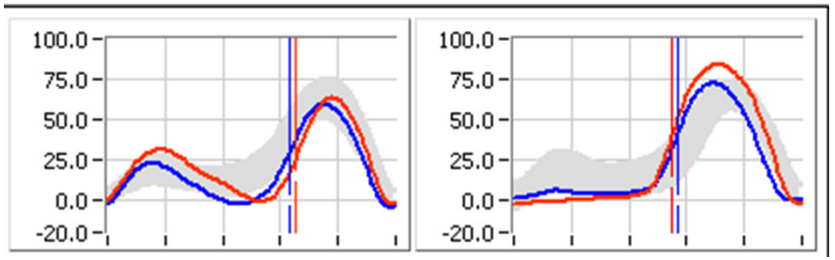
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



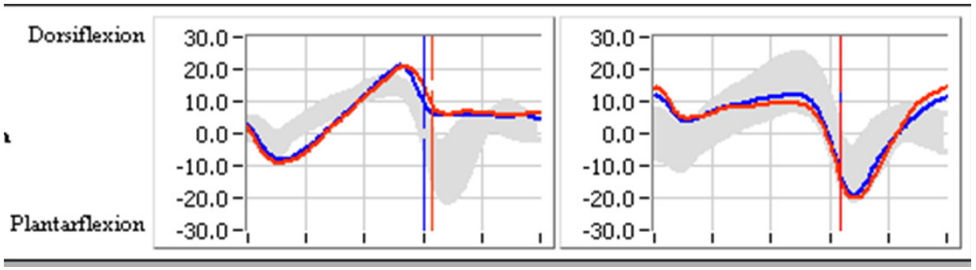


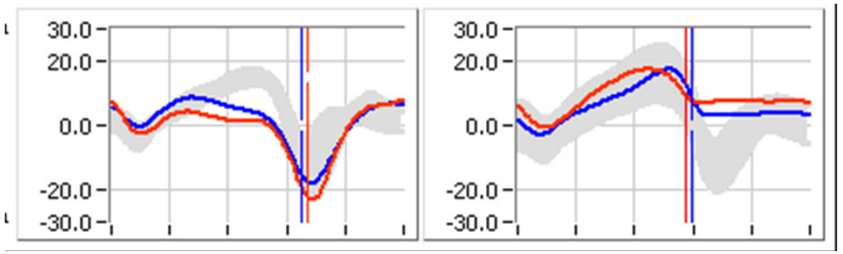
Ischial Containment

Sub-Ischial

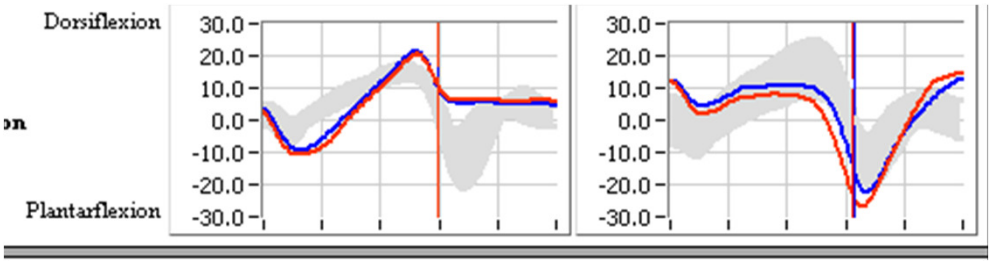
Ankle Dorsi/Plantar Flexion

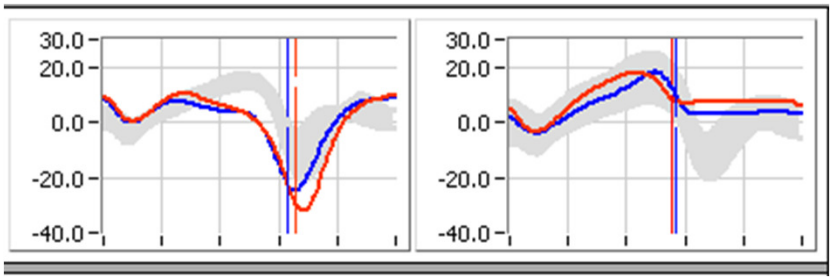
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





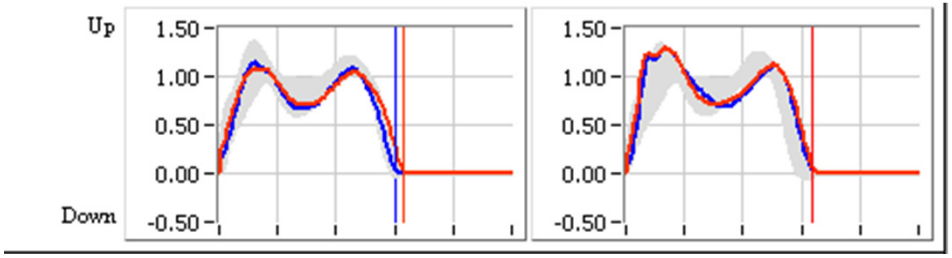
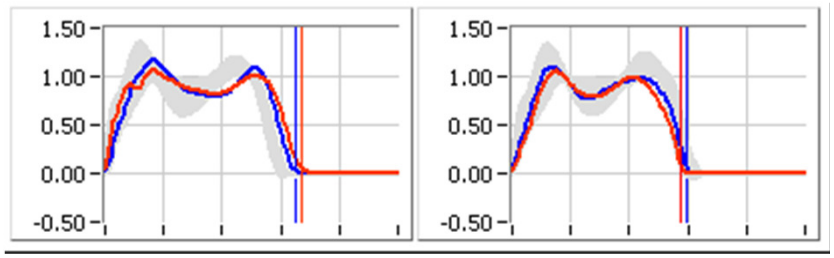
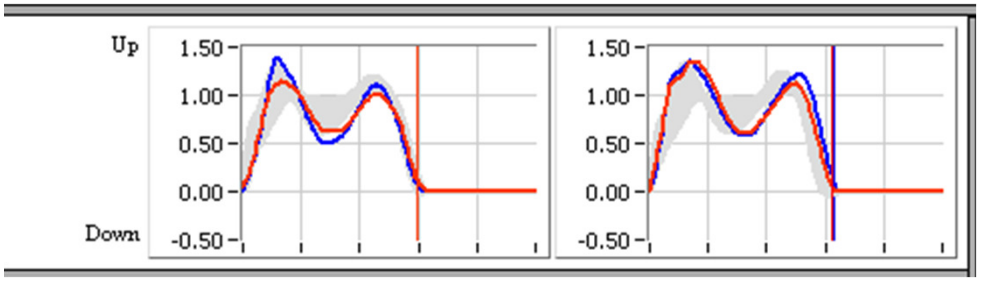
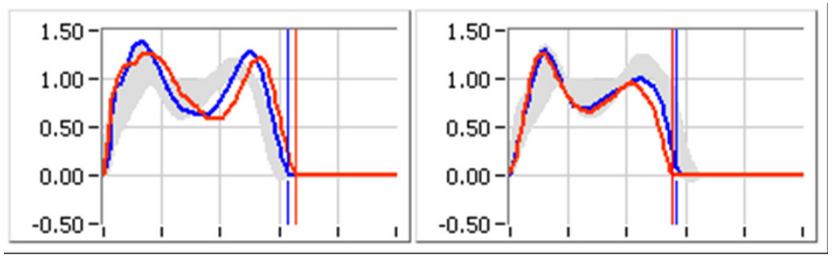
Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Ischial Containment Sub-Ischial

Vertical Ground Reaction Force

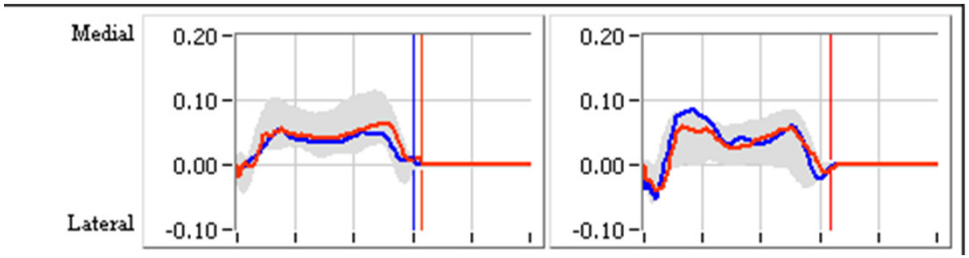
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic
			
Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic
			

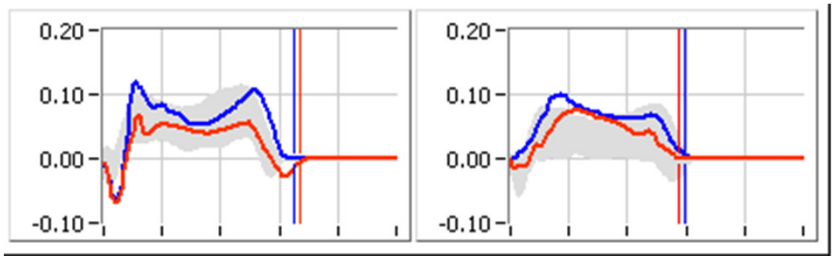
Ischial Containment

Sub-Ischial

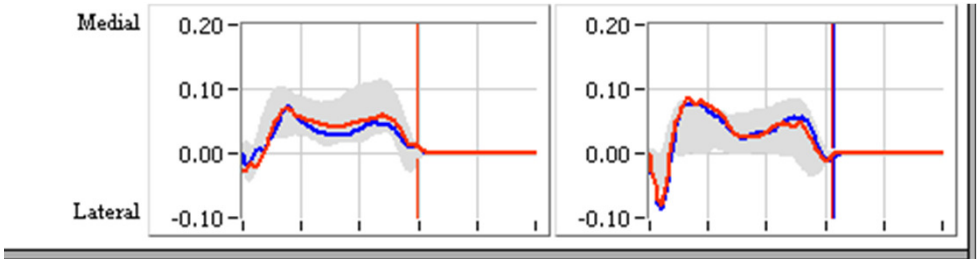
Mediolateral Ground Reaction Force

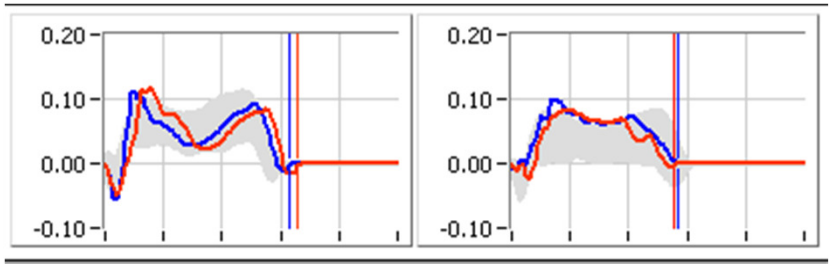
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

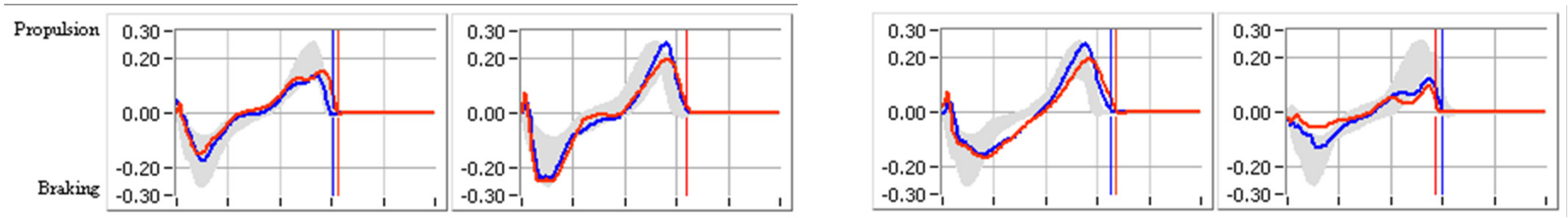




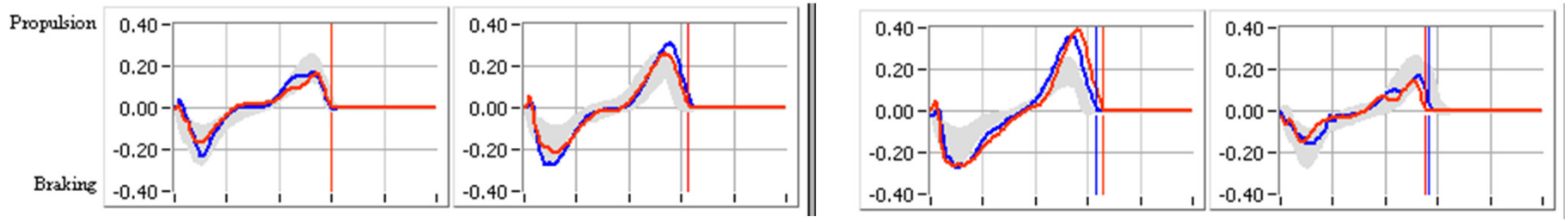
Ischial Containment Sub-Ischial

Fore-Aft Ground Reaction Force

Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



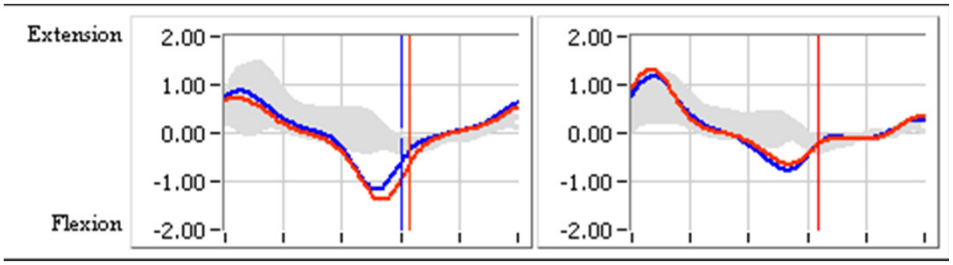
Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

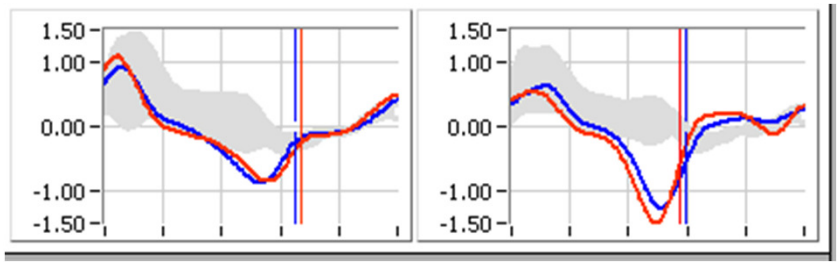


Ischial Containment Sub-Ischial

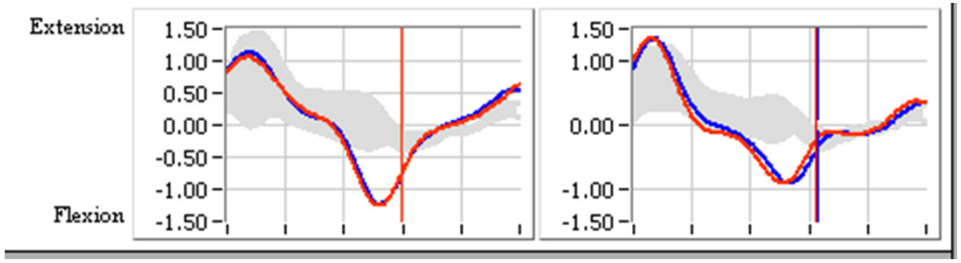
Sagittal Hip Moment

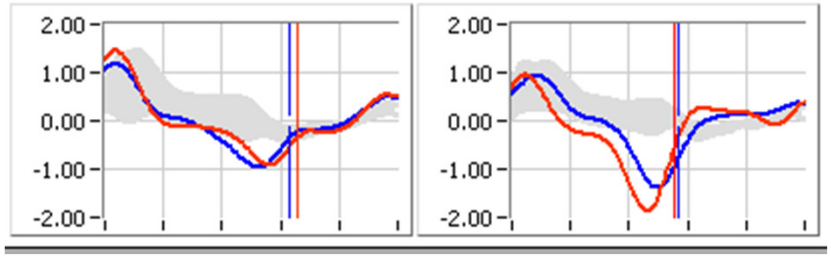
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



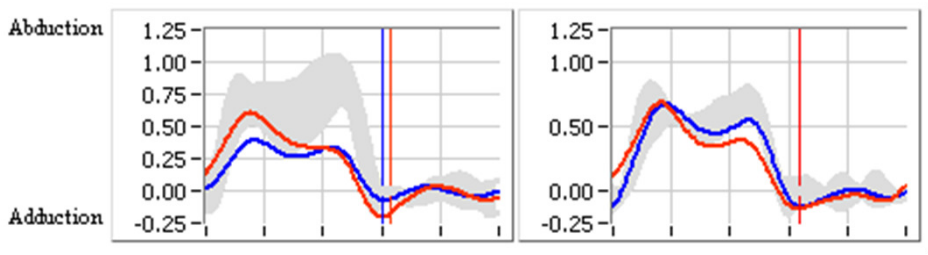


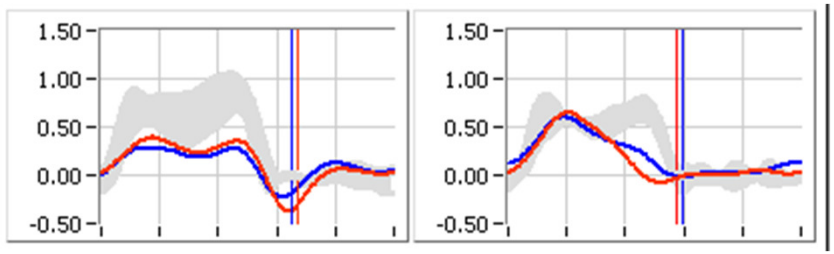
Ischial Containment

Sub-Ischial

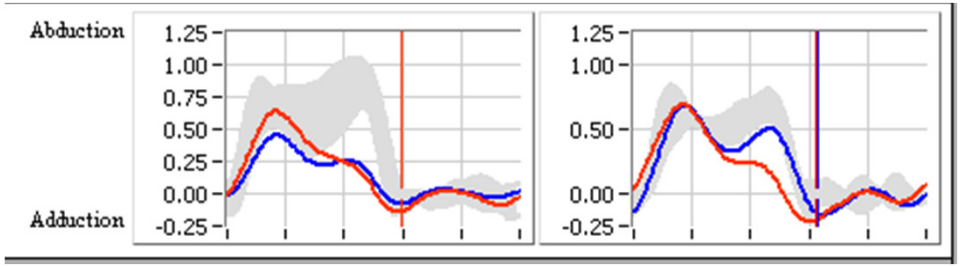
Coronal Hip Moment

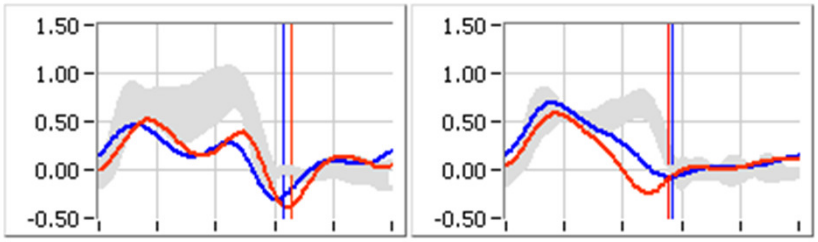
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



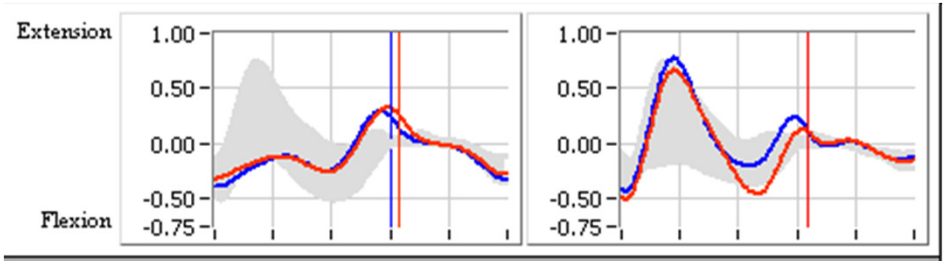


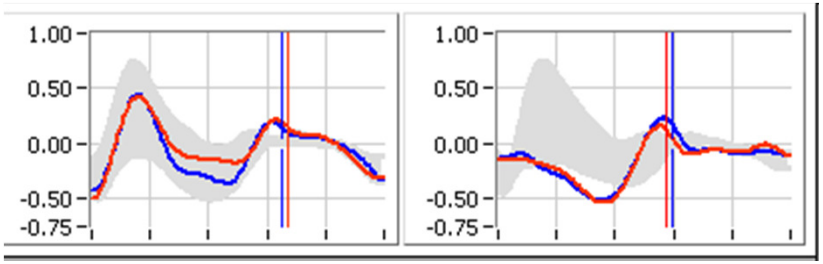
Ischial Containment

Sub-Ischial

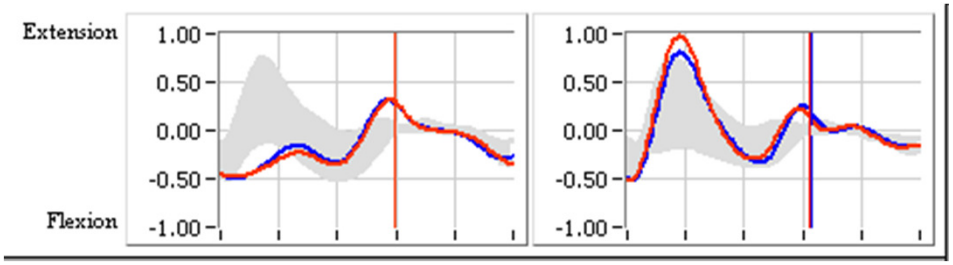
Sagittal Knee Moment

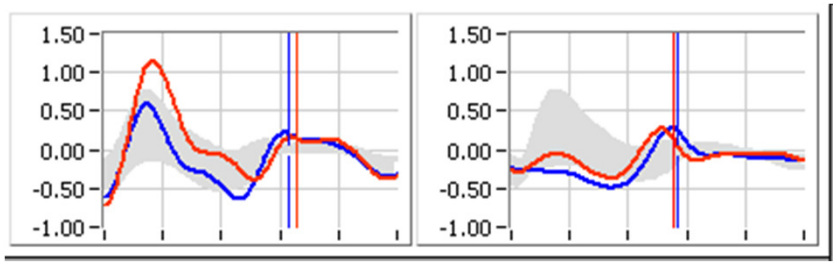
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic



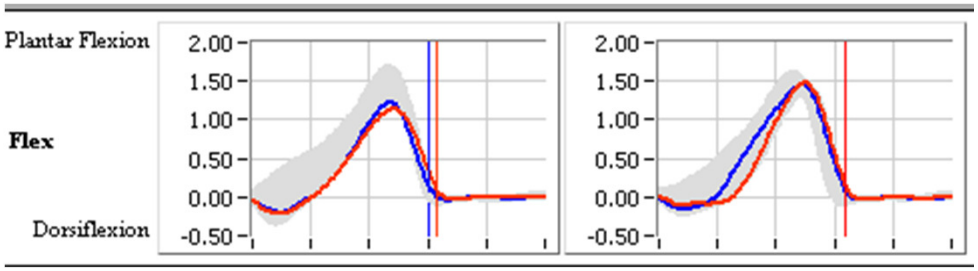


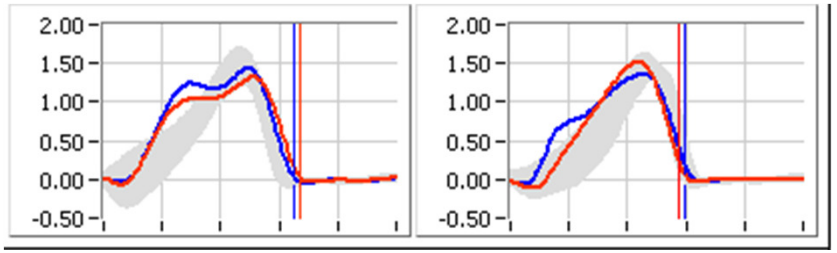
Ischial Containment

Sub-Ischial

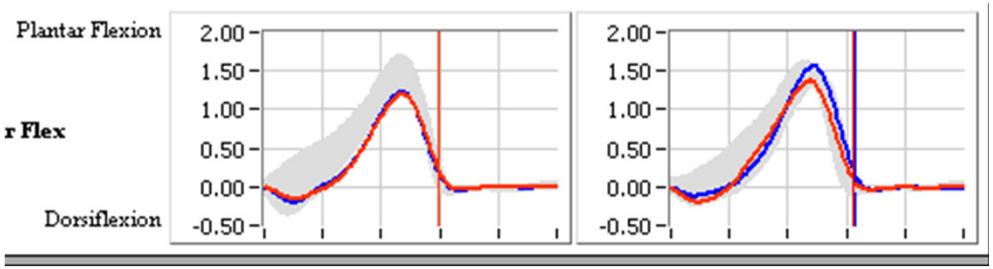
Sagittal Ankle Moment

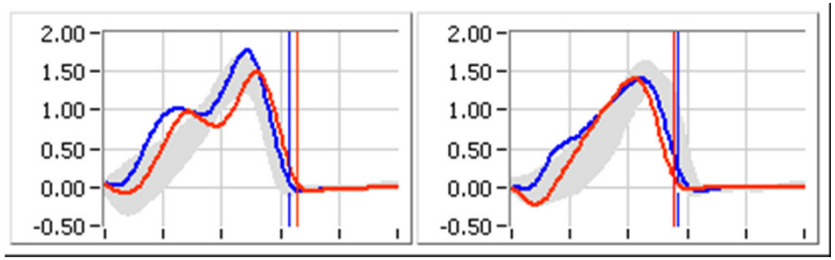
Subject 1		Subject 2	
Normal Walking Speed		Normal Walking Speed	
Prosthetic	Sound	Sound	Prosthetic





Fast Walking Speed		Fast Walking Speed	
Prosthetic	Sound	Sound	Prosthetic

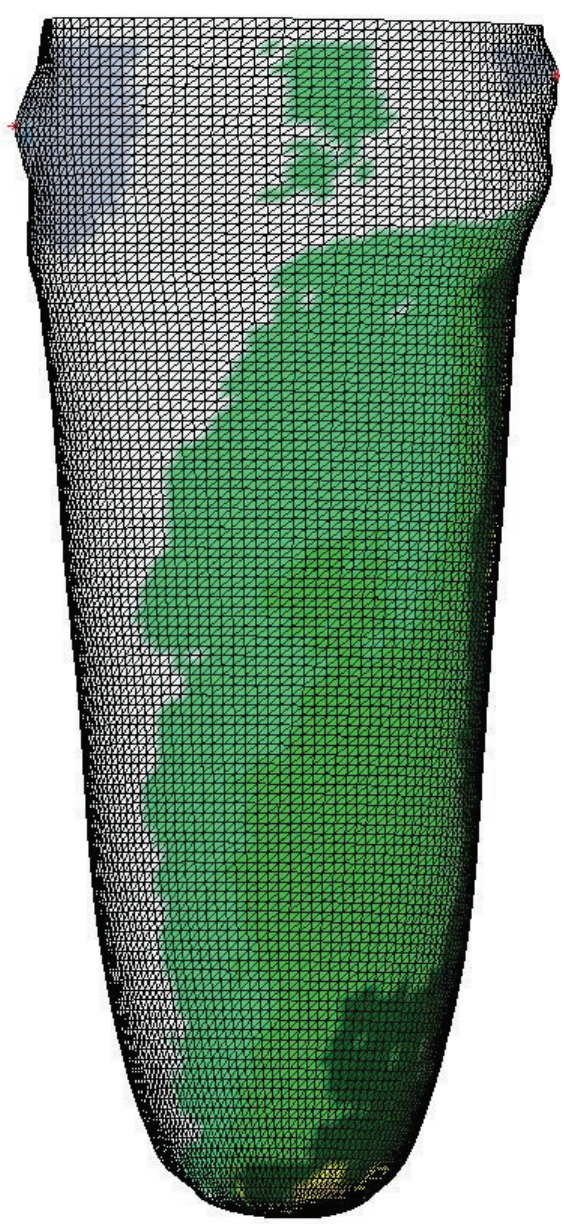




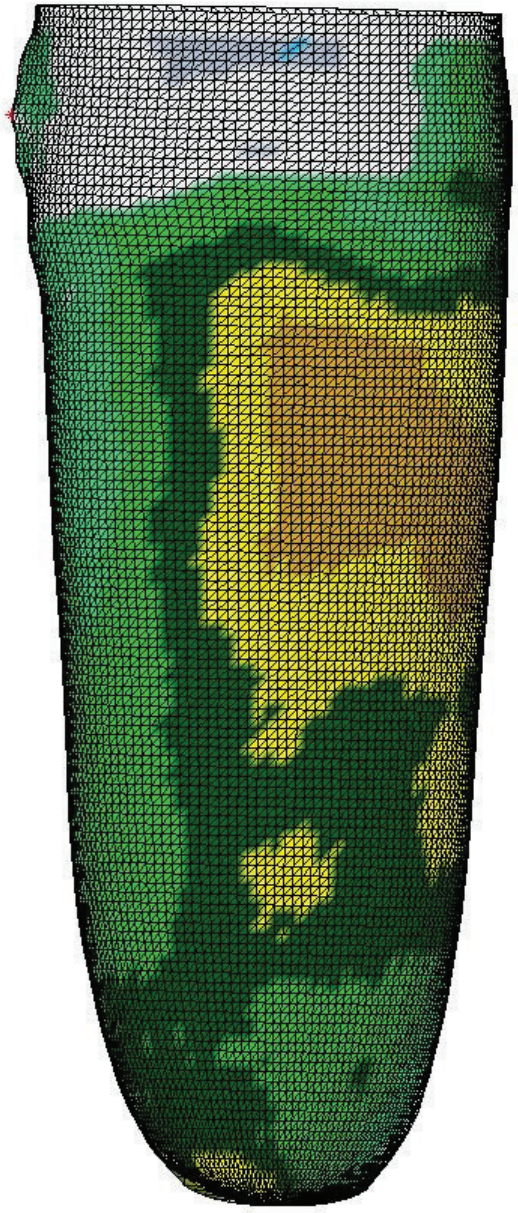
Ischial Containment Sub-Ischial

Appendix F

Rectification Patterns

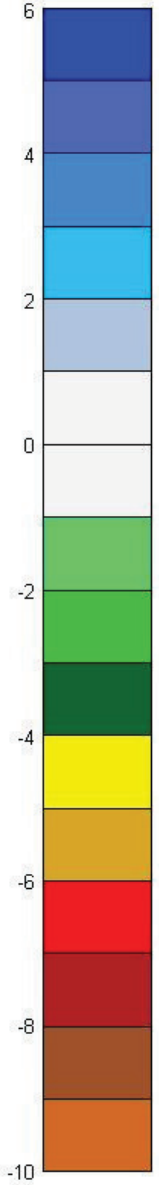


Anterior View

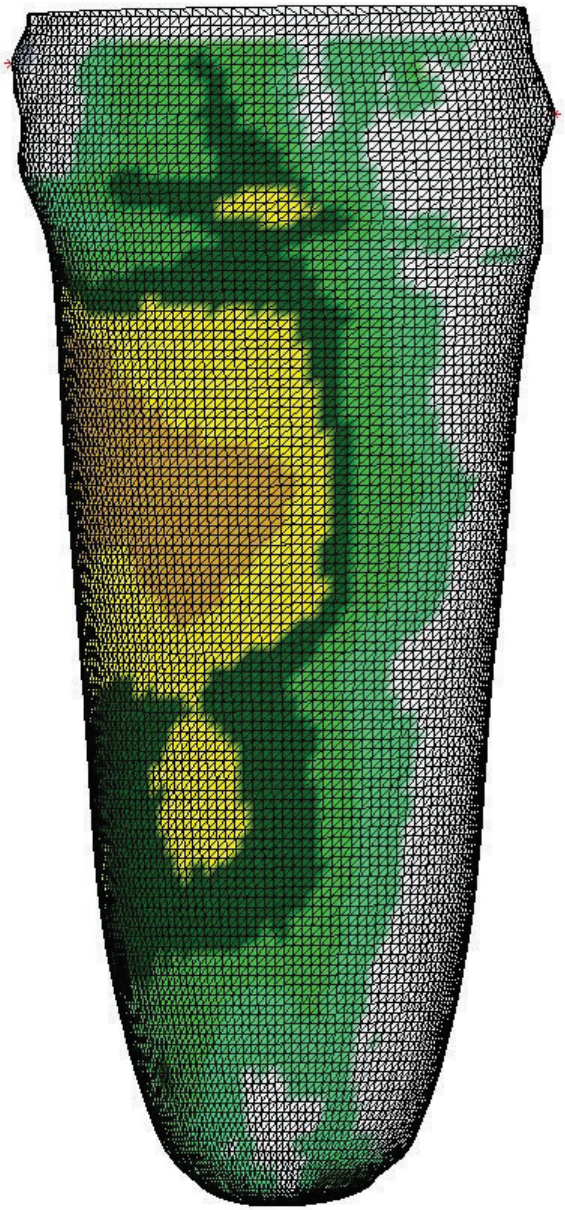


Lateral View

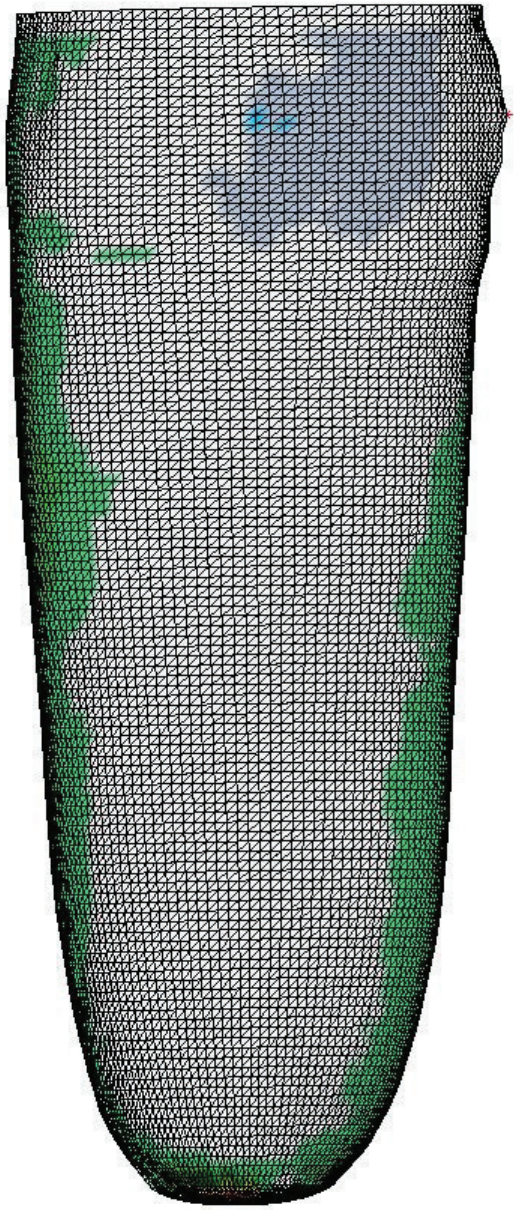
Modified shape with color coding to indicate the amount of rectification. Negative numbers represent material being removed from the unmodified shape. Positive numbers mean addition of material. If the alignment is good, then there should be minimal to no blue regions. Units for the scale are millimeters.



Rectification Patterns

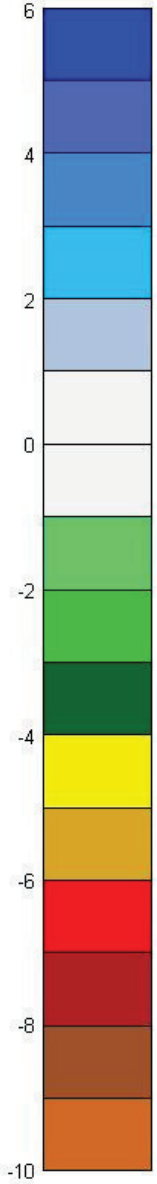


Posterior View



Medial View

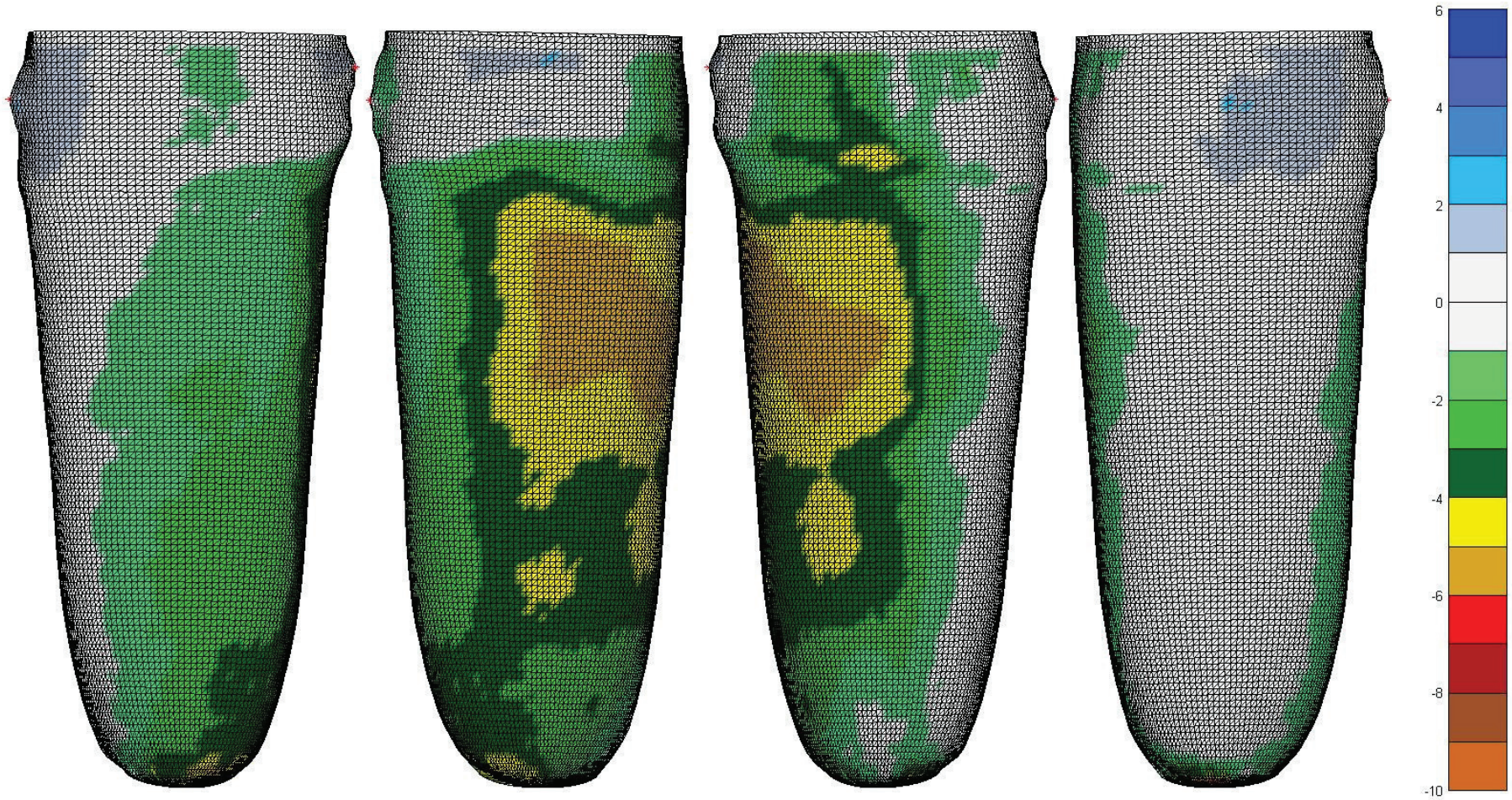
As the color coding indicates, this shape has a maximum reduction of 5-6 mm along the lateral and posterior surfaces.



Rectification Patterns

Anterior View Lateral View Posterior View Medial View

Cast #2



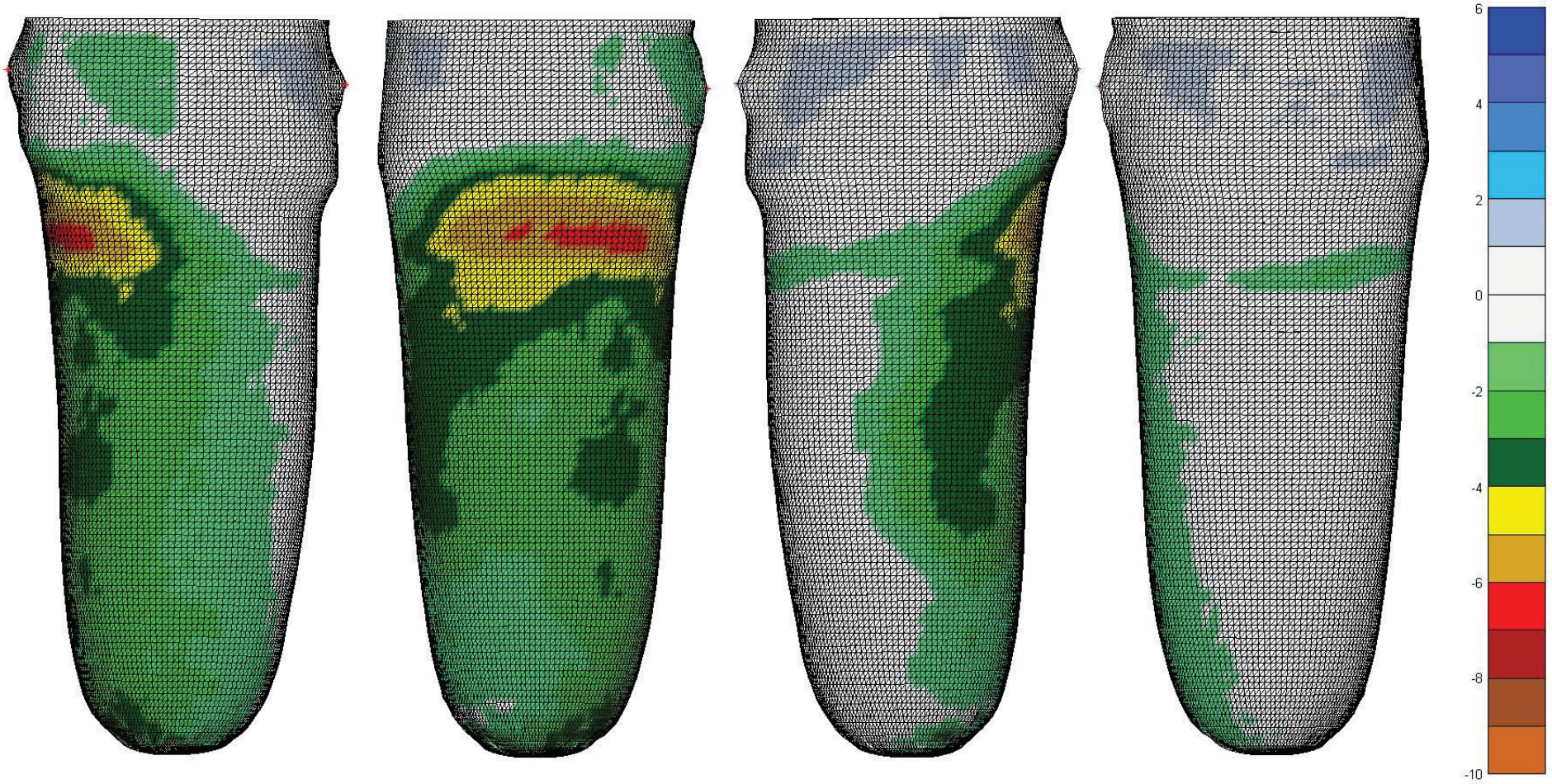
Anterior View

Lateral View

Posterior View

Medial View

Cast #3



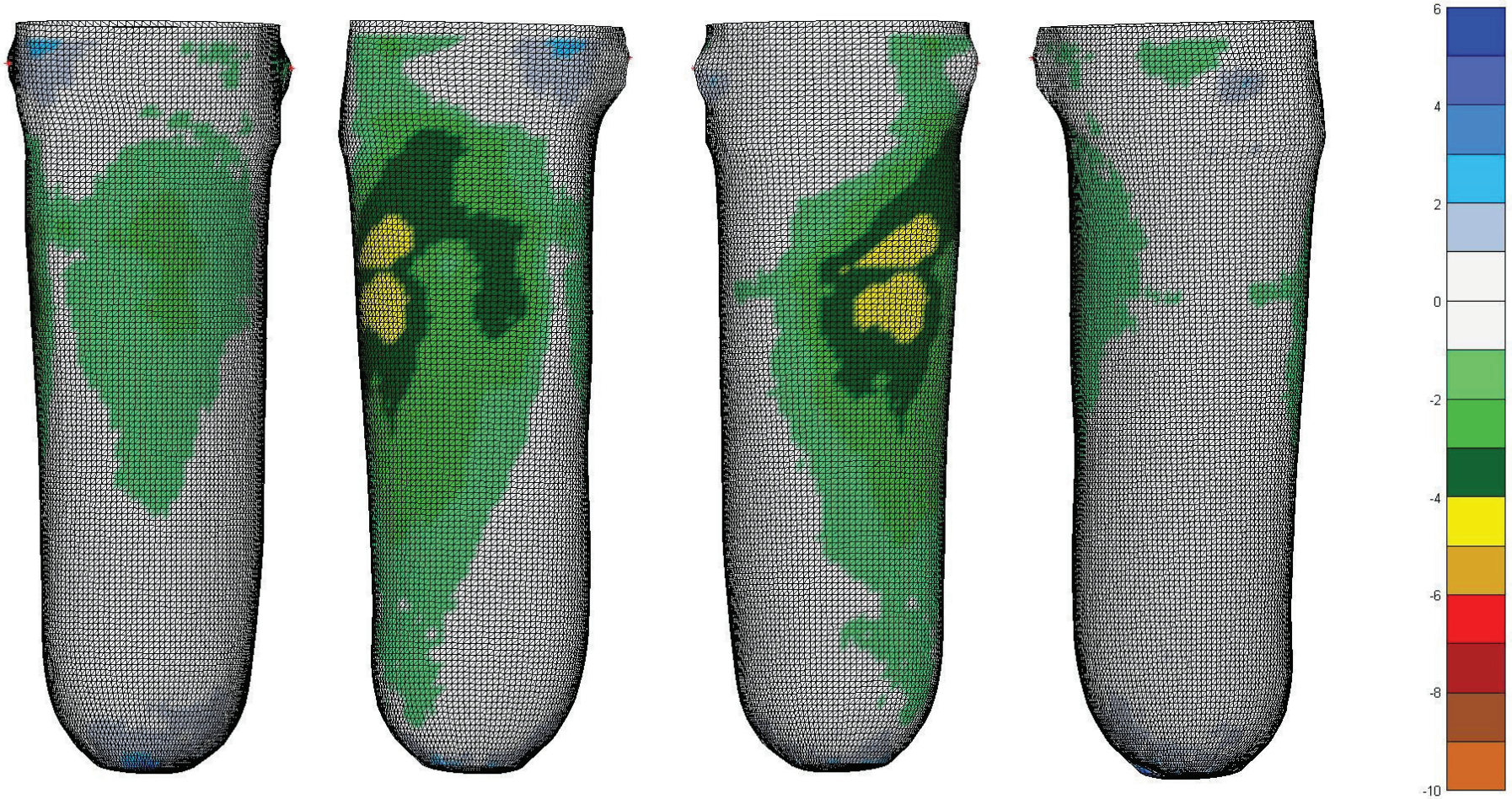
Anterior View

Lateral View

Posterior View

Medial View

Cast #4



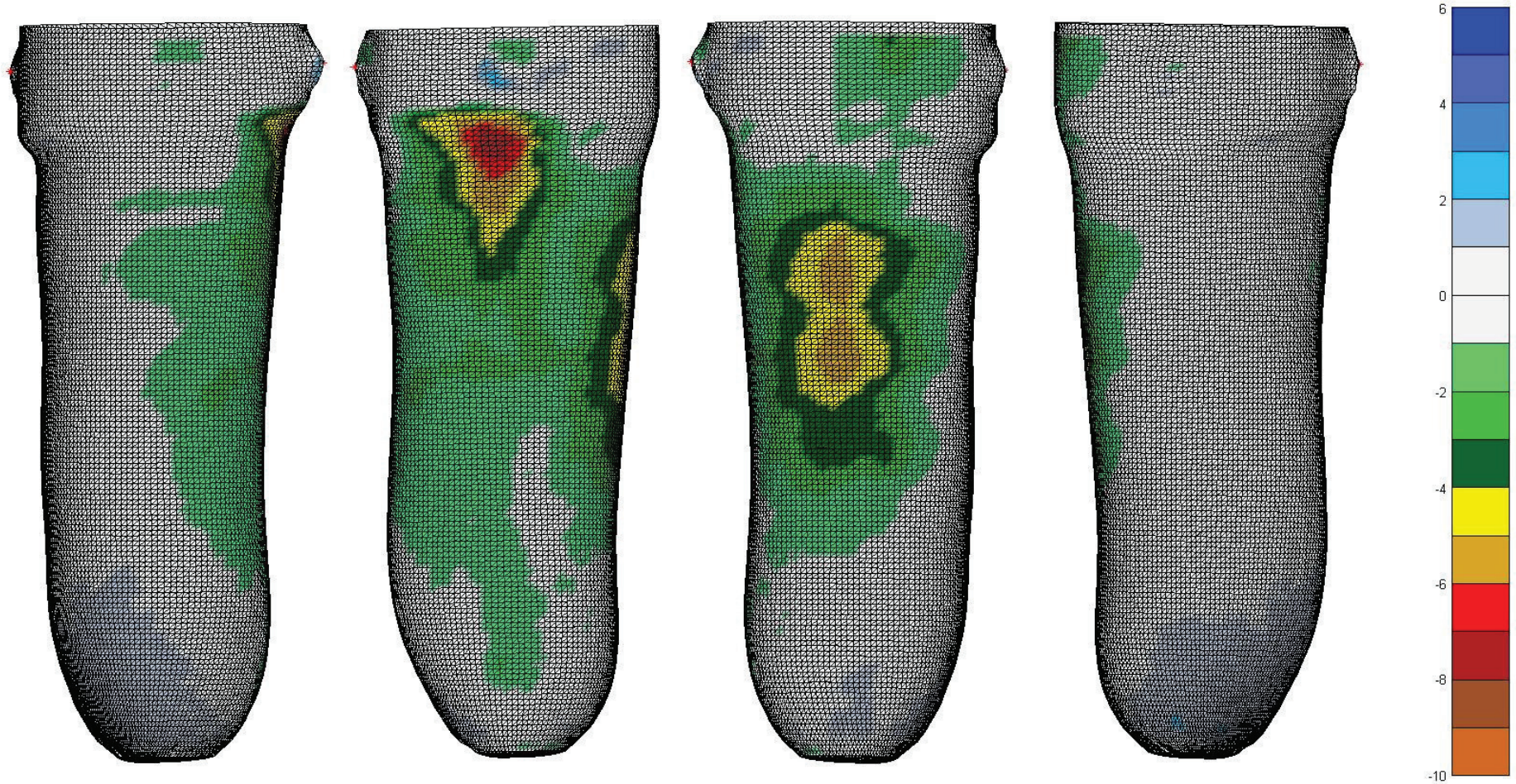
Anterior View

Lateral View

Posterior View

Medial View

Cast #5



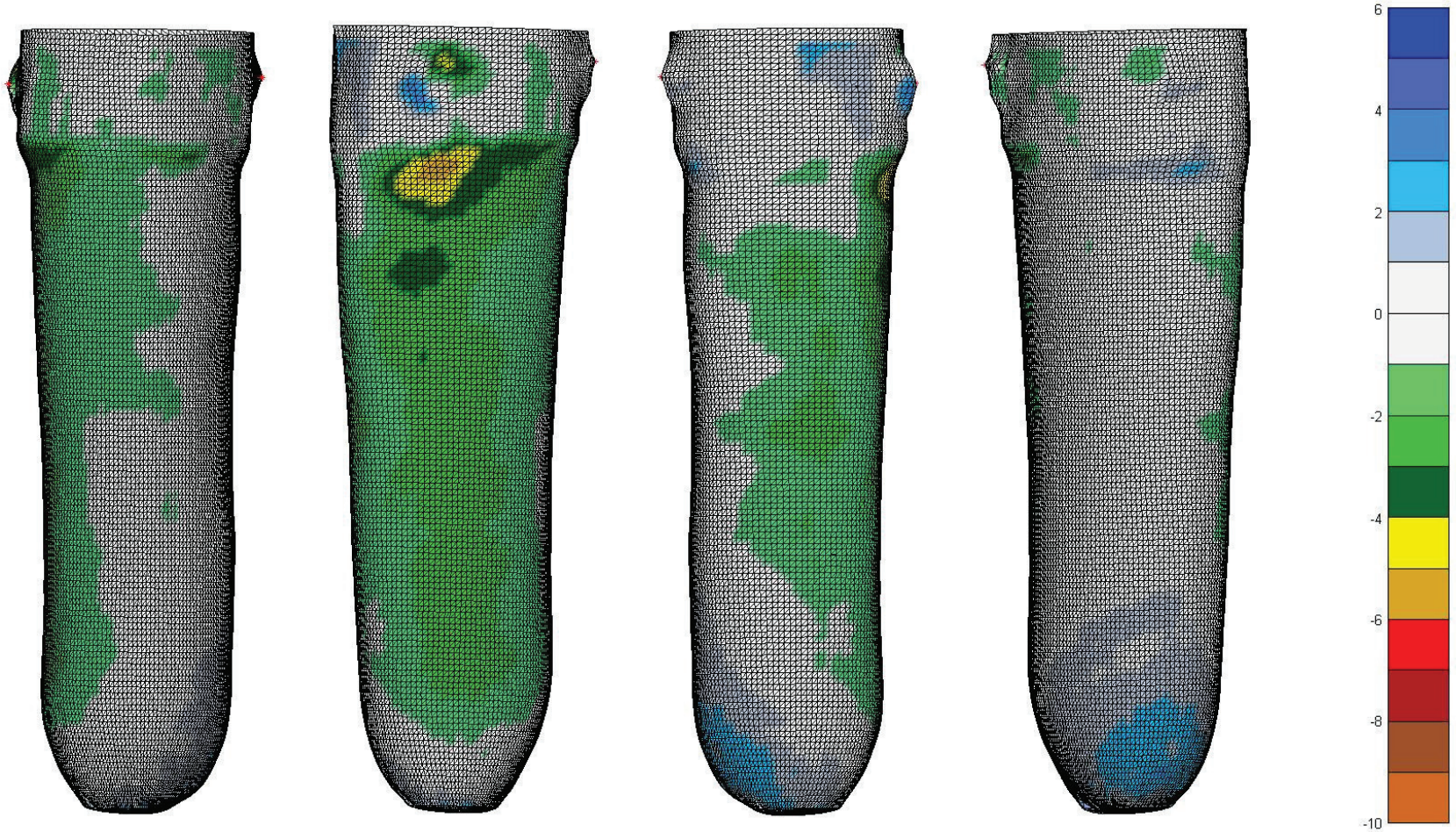
Anterior View

Lateral View

Posterior View

Medial View

Cast #8



Anterior View

Lateral View

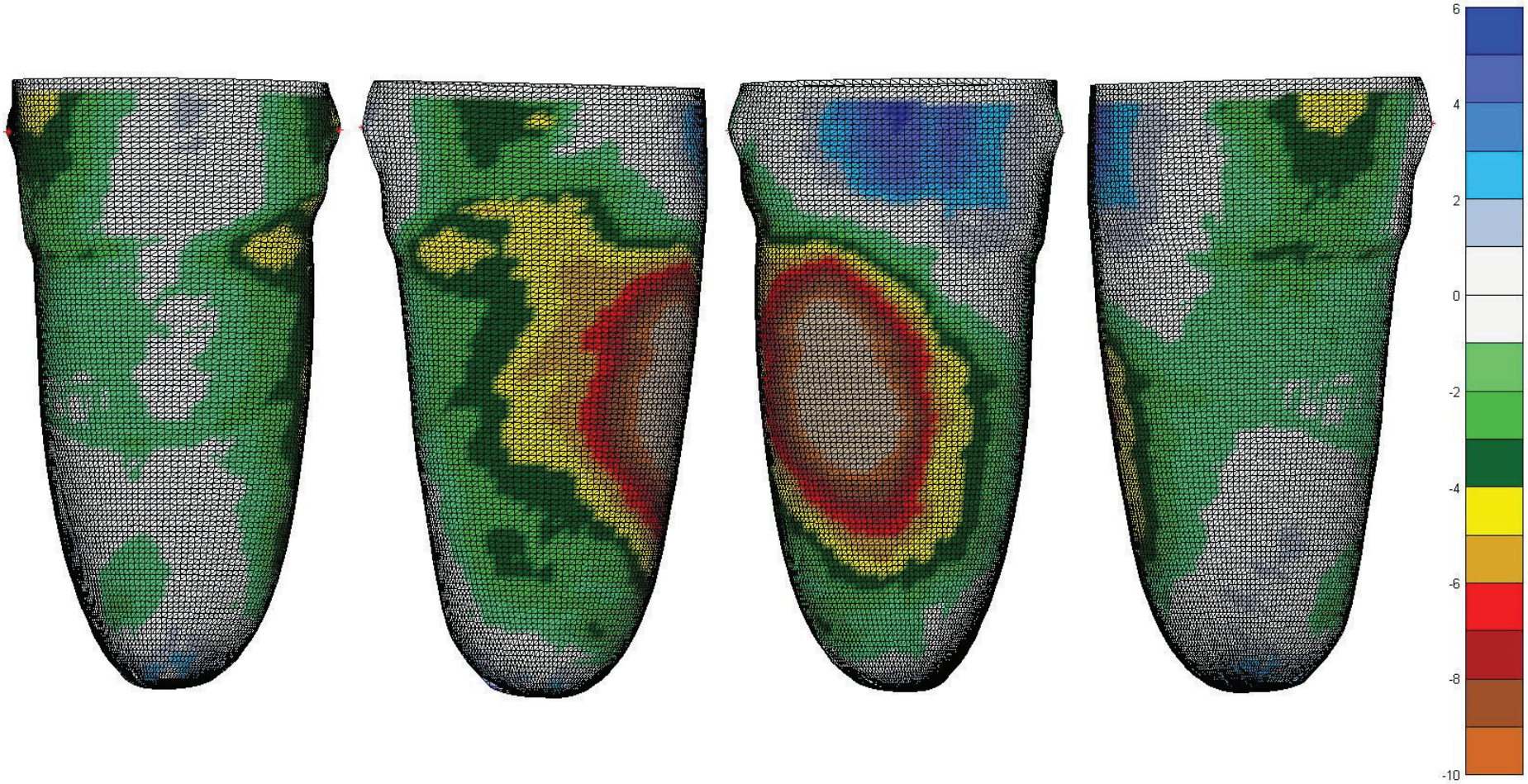
Posterior View

Medial View

Cast #9

Anterior View Lateral View Posterior View Medial View

Cast #11



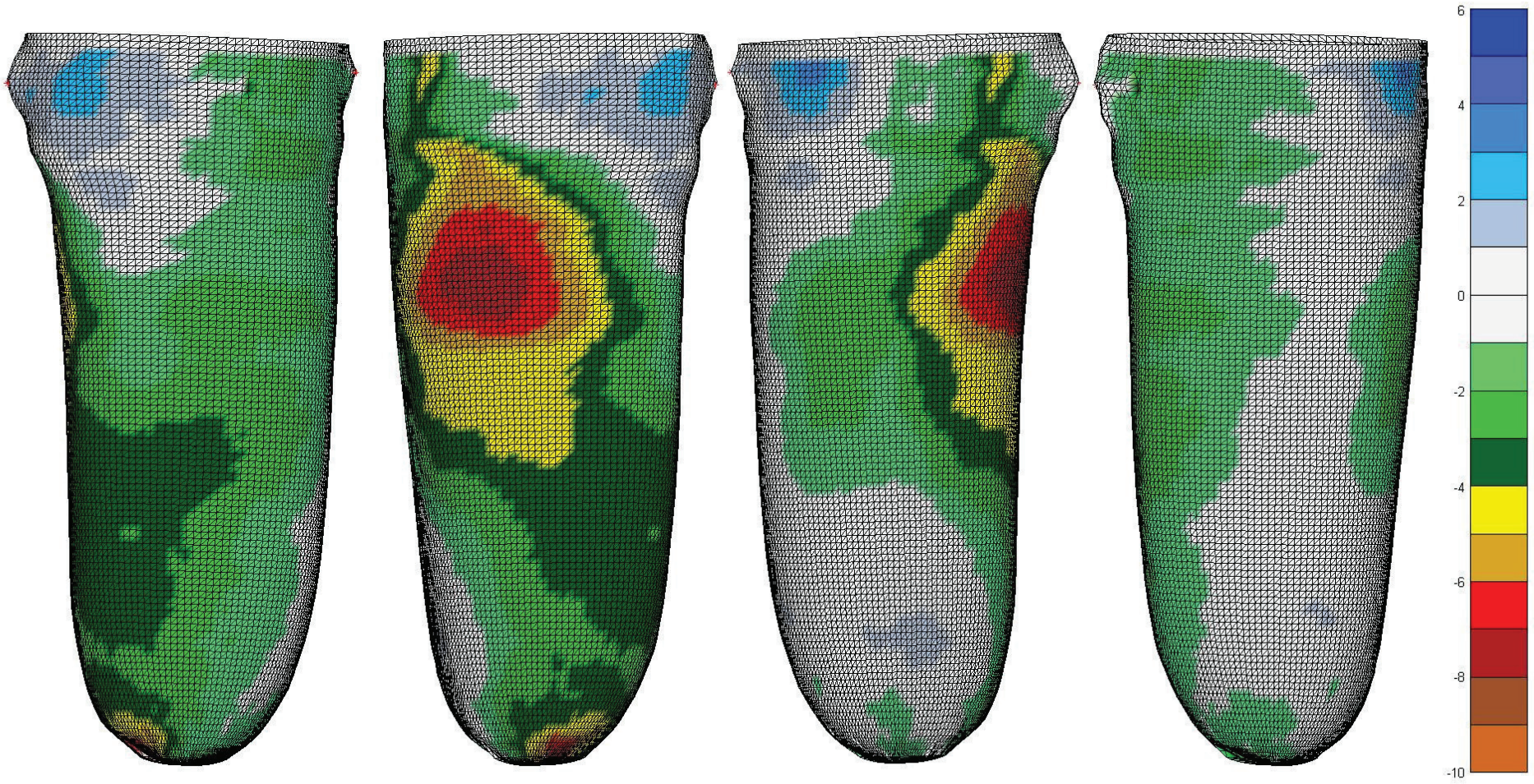
Anterior View

Lateral View

Posterior View

Medial View

Cast #12



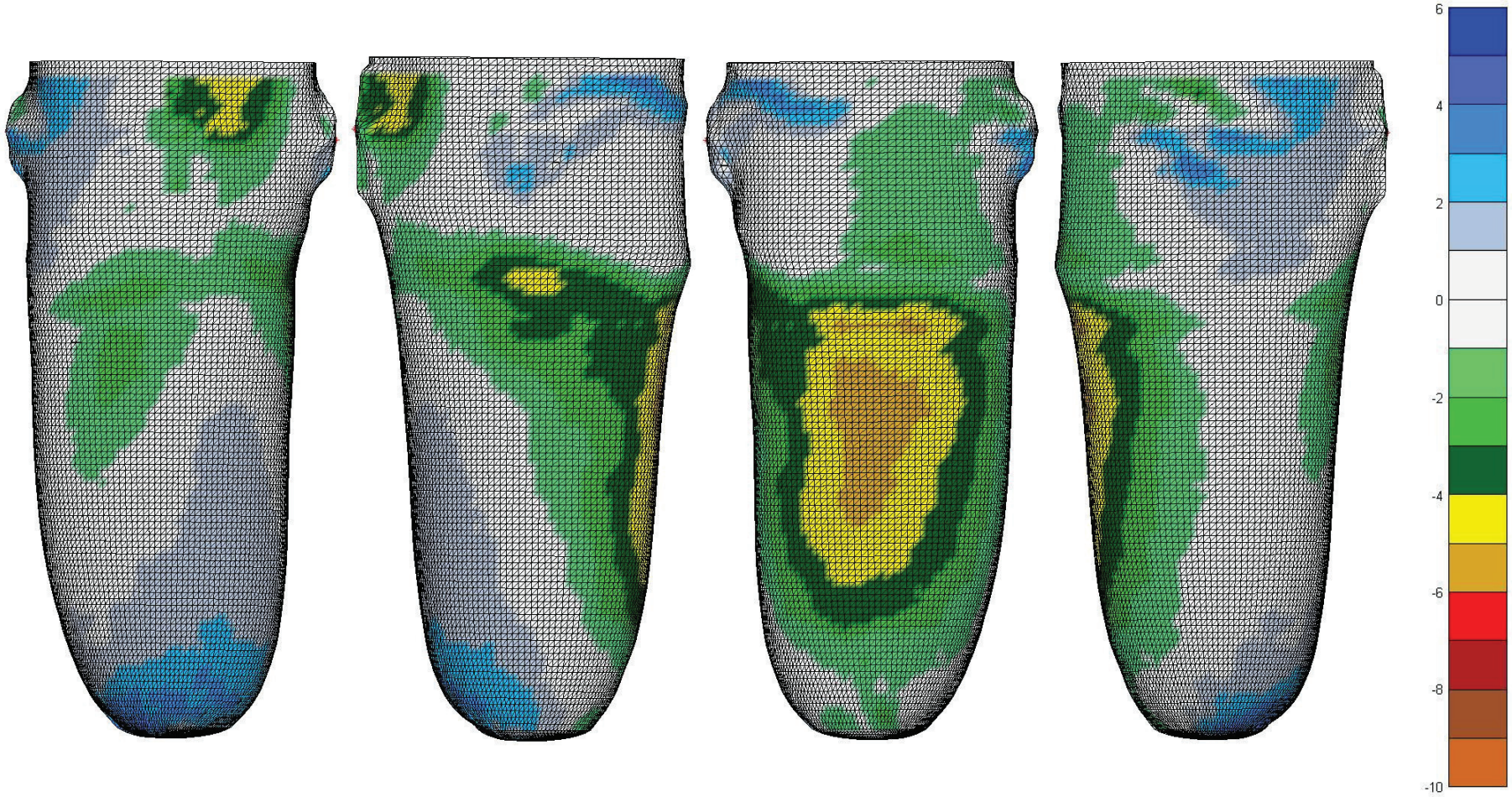
Anterior View

Lateral View

Posterior View

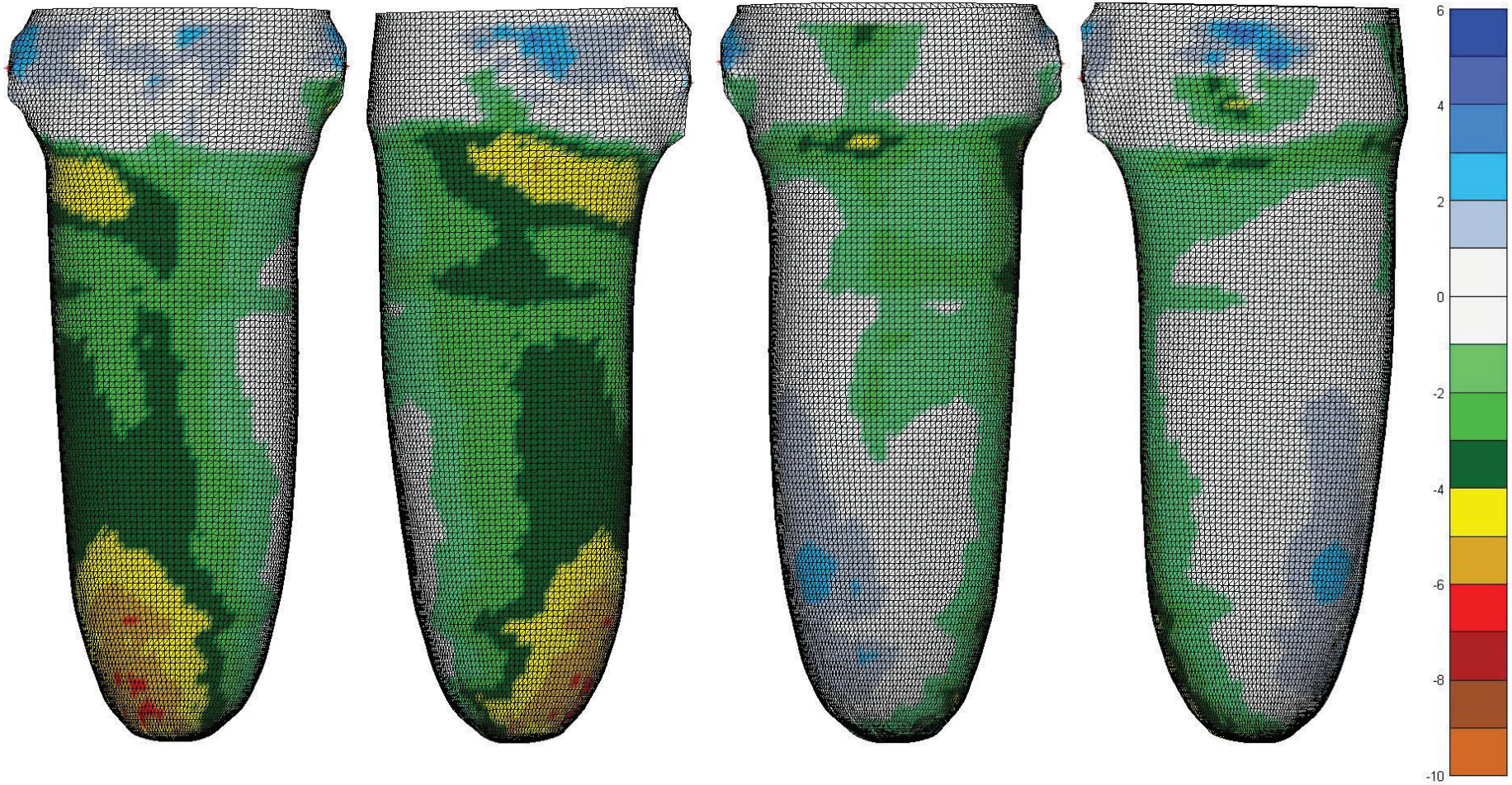
Medial View

Cast #15



Anterior View Lateral View Posterior View Medial View

Cast #16



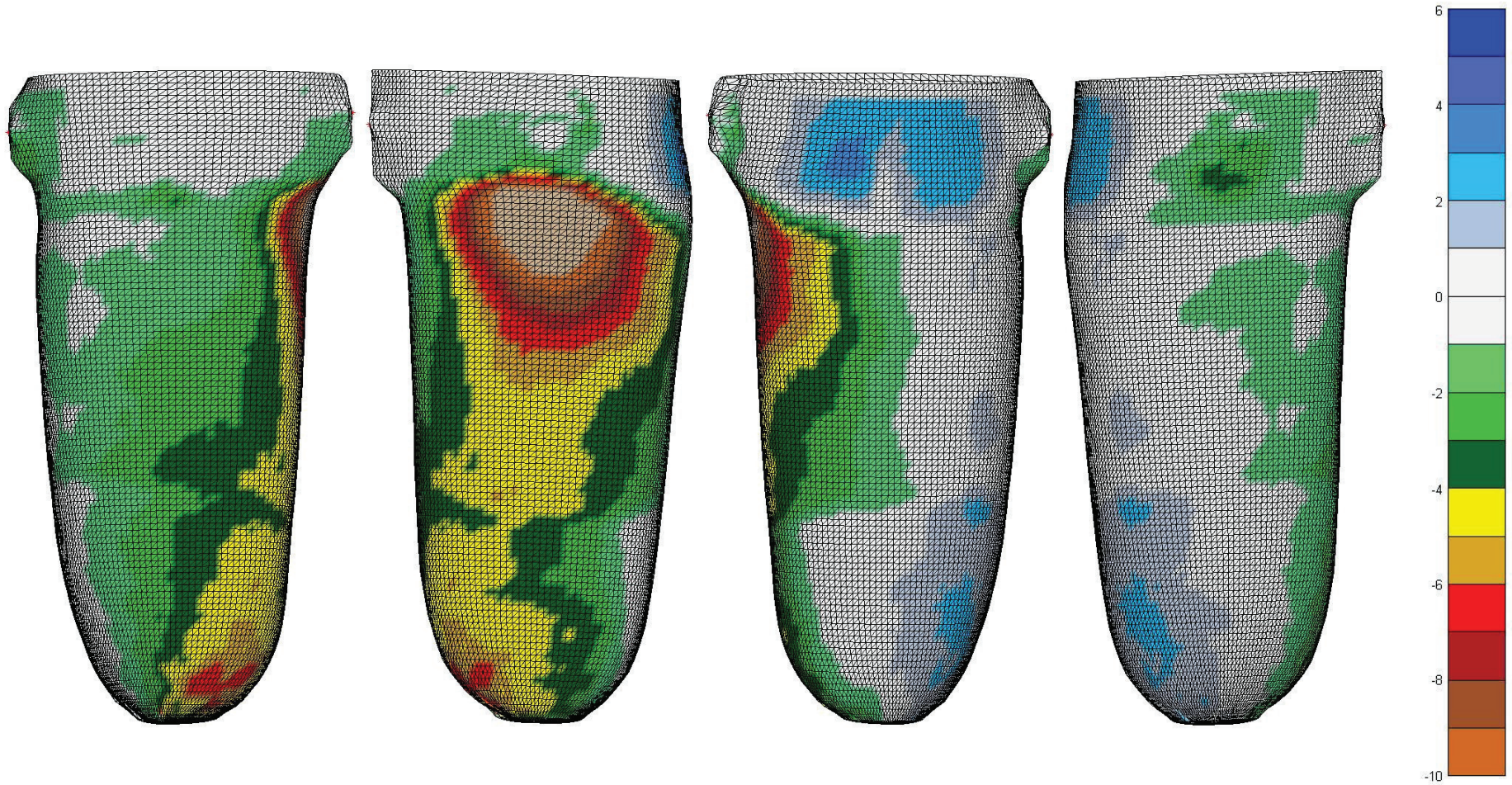
Anterior View

Lateral View

Posterior View

Medial View

Cast #18



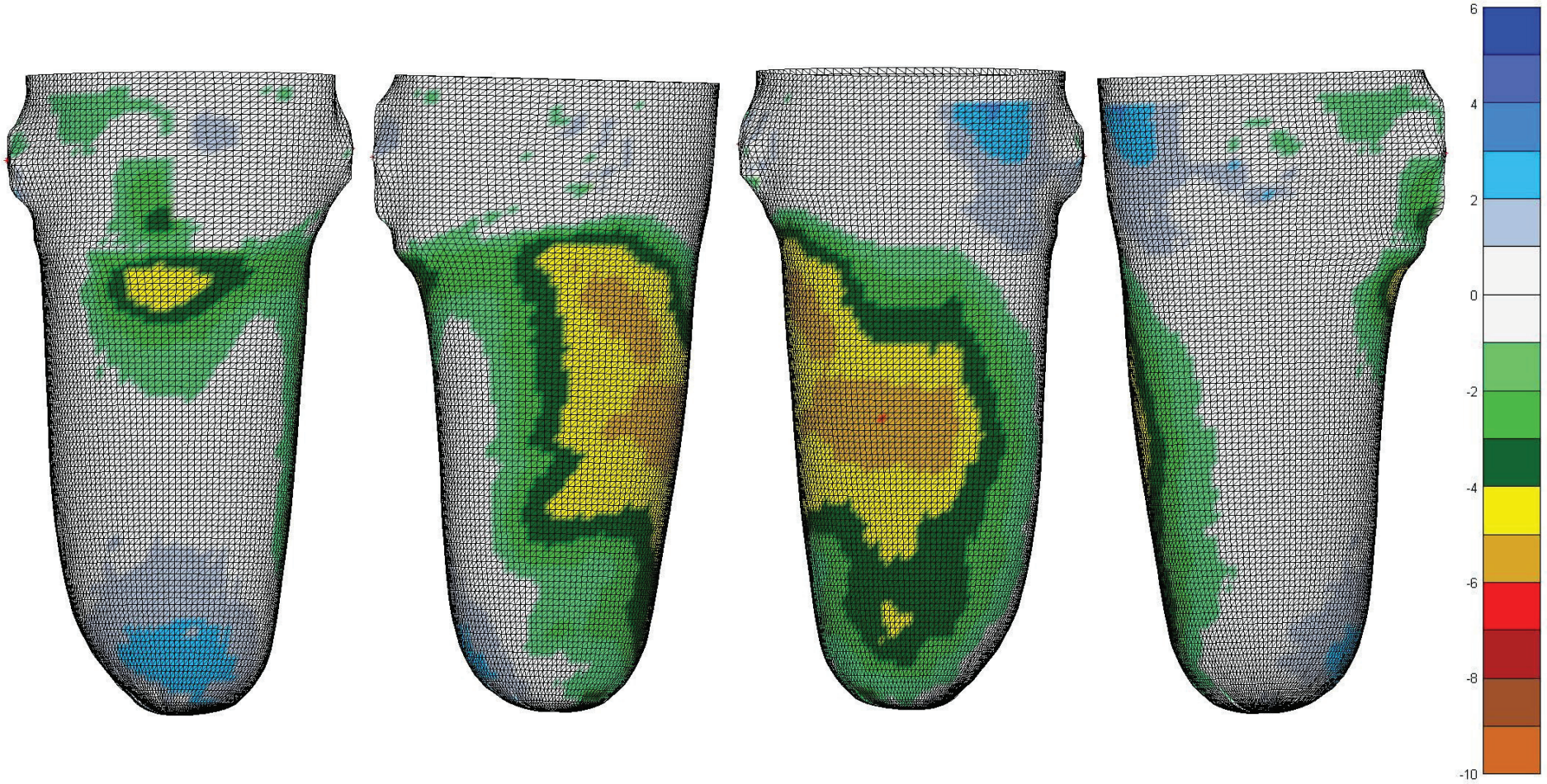
Anterior View

Lateral View

Posterior View

Medial View

Cast #19



Anterior View

Lateral View

Posterior View

Medial View